A Retrospective, Observational Study of Medico-legal Cases against Obstetricians and Gynaecologists in South Africa's Private Sector

by

Bettina Taylor

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Supervisor: Associate Professor Susan Cleary
Health Economics Unit
University of Cape Town

Declaration

I, Bettina Taylor, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

South Africa is experiencing a medico-legal crisis that is threatening the delivery of essential health care services, especially relating to maternal and fetal health. In the private sector, professional indemnity premiums for obstetricians to provide insurance cover in the event of medico-legal challenges have increased more than 10-fold in a 10-year period. In the State, exponential increases in contingent liabilities for claims due to alleged negligence are usurping health care budgets allocated towards the delivery of health care, with about half of these claims relating to obstetrics and gynaecology and three quarter of latter to cerebral palsy for reasons of alleged hypoxic brain injury of the newborn. Despite the ominous implications of these developments for the supply side of health care, there is a scarcity of information in terms of contributing factors. Whilst many assume that the main driving force of burgeoning professional indemnity premiums for obstetricians and gynaecologists in the private sector have also been as a result of claims for cerebral palsy, there are no empirical data to explain developments over recent years and guide risk management interventions in this regard.

To understand claim trends and identify potential predictors of patient dissatisfaction that result in engagement of the regulatory and legal system in the private sector, obstetric and gynaecological medico-legal data recorded by Constantia Insurance Limited, a local professional indemnity provider, were analysed. Other than confirming a steep increase in medico-legal notifications for obstetric- and gynaecology-related complaints from about 2003 to 2012, a high proportion of number of claims and paid settlements for gynaecology relative to obstetric-related cases was noted. This is contrary to international and public sector experiences, where number of demands relating to obstetrics consistently exceed those associated with gynaecological care. This finding, together with the fact that the majority of pay-outs on behalf of doctors related to surgical complications, especially unintended intraoperative injuries to internal organs and vessels, calls for further research into the clinical outcomes of private gynaecological practice, as well as potential review of aspects of surgical training standards and accreditation in gynaecology and consideration of surgical mentorship programmes. The latter is particularly relevant in the context of surgical

registrars having expressed concerns about their readiness to practice independently following specialist graduation.

Whereas claims for severe neurological injury of the newborn constituted less than 15% of all claims settled on behalf of obstetricians and gynaecologists entered into the study, they accounted for about half of all known paid settlements relating to pregnancy-related care. Whilst not dominating in terms of claim frequency overall, they nevertheless are an important focus area for risk management interventions, given the high quantum of demand typically associated with these cases. In this regard, more research into the etiology of errors is required, including the contribution of nursing and other system failures that could not be quantified adequately as part of this research project. Another important finding was the disproportionate contribution of medico-legal risk by a small cohort of practitioners, which suggests a need for doctor-focused support and interventions, including effective peer review and regulatory oversight by the Health Professions Council.

To reverse the high financial burden of professional indemnity fees and fear of litigation amongst private sector obstetricians and gynaecologists, multidimensional risk management interventions, which include enhancements at the point of care, are required. If medico-legal trends and their negative consequences are to be reversed, medico-legal hotspots should become an important source of information and consideration in the development of solutions aimed at preventing human error and strengthening the healthcare system in terms of improved patient safety and satisfaction.

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Abbreviations and terminology

BetterObs	This is a programme launched by SASOG with the objective of promoting safe ante- and intrapartum care and with that also mitigating the risks of a successful lawsuit. With regards to optimising clinical care, pillars of the programme include clinical guidelines and protocols, regular morbidity and mortality meetings and professional society-driven peer review to handle allegations of unprofessional conduct, repeated misconduct or members not following guidelines or protocols.
BHF	Board of Healthcare Funders
Board of Healthcare Funders	This is a not-for-profit company that represents the interests of the private funding industry in Southern Africa.
Brachial plexus	The brachial plexus is a network of nerves in the neck that can be damaged during a difficult delivery where there is excessive stretching of the neck and/or pulling of a baby's upper arm. It results in variable weakness of the affected limb and hand.
Cardiotocography	Cardiotocography, also known as electronic fetal monitoring, is a technical means of recording fetal heartbeat and uterine contractions. It is used to assess fetal well-being.
Case type	It is the status of any incident notified by the insured doctor to his/her professional indemnifier including a notification of circumstance without there being a formal complaint or investigation; a formal written complaint; an inquest; a HPCSA or OHSC complaint; a request for records; a letter of demand or summons.
Cerebral palsy	This is a group of movement and posture disorders caused by disturbances in the developing fetal or infant brain and which may be associated with multiple other developmental disorders. Birth-related hypoxia of the newborn is one of many causes.
Claim	A claim refers to a demand for compensation from a health care provider, typically for reasons of alleged negligence in the diagnosis, treatment and/or care of a patient.
Claims-made cover	A type of insurance cover where protection against claims is only offered for incidents reported to the insurer whilst premiums are being paid. It provides medico-legal cover for incidents that both occur and are reported during the policy period, regardless of when a claim is received.
Closed claim	A claim can be closed for reasons of having been withdrawn or resolved in favour of the plaintiff or the defendant following a legal process.
CMSA	Colleges of Medicine of South Africa
Colleges of Medicine of	This is a not-for-profit company founded by members of the medical

South Africa	profession. It supports the Health Professions Council in defining training programmes and is currently the contracted National Examining Body of the Health Professions Council.
Constantia Insurance Company Limited	A South African insurance company registered as a financial service provider, selling professional indemnity cover to health care practitioners.
CTG	Cardiotocograph
Defendant	The defendant is the individual (or company/institution) sued or accused in a court of law.
Demand	See 'claim'
Erb's palsy	It is a paralysis of the arm as a result of an injury to parts of the brachial plexus (see above), typically as a result of shoulder dystocia during a difficult birth.
FCOG	Fellowship of the College of Obstetricians and Gynaecologists
Gynaecology	Gynaecology is that part of medical practice that is focused on the female reproductive system and the breasts.
Health Market Inquiry	The Health Market Inquiry was a formal, consultative investigation by the Competition Commissioner into the general state of competition in South Africa's private health care sector.
Health Professions Council of South Africa	This body guides and regulates the health profession in aspects pertaining to education and training, professional conduct and ethical behaviour.
HMI	Health Market Inquiry
HPCSA	Health Professions Council of South Africa
Hysterectomy	Hysterectomy is the surgical removal of the uterus. Different surgical approaches are available, including open abdominal surgery, vaginal resection and/or laparoscopy.
Incident date	Date on which an incident relating to a medico-legal case occurred.
Inquest	An inquest is a judicial inquiry to determine the cause of a patient's death where this is unexpected or unexplained.
Laparoscopy	Laparoscopy, a form of minimally invasive surgery, is an operation performed in the abdomen or pelvis via small cuts and the aid of a camera. It can be used to diagnose and/or treat diseases. It is a modern surgical technique also known as keyhole surgery.
Medical malpractice/ negligence	Medical malpractice is a legal term that refers to the deviation by a health care practitioner from standards in his or her professional field that results in injury to a patient.
Medical Protection Society	A UK-based mutual organization that offers professional indemnity cover to South African health care practitioners on the basis of

	membership that provides access to discretionary benefits as set out in the Memorandum and Articles of Association.
MIS	Minimally invasive surgery (also see laparoscopy)
MPS	Medical Protection Society
National Quality Forum	This is a US-based not-for-profit, membership-based organization that works towards the ongoing improvement of quality of health care. Quality measures defined and adopted by the organization are used by the federal government, states and private sector organizations in the United States.
Natmed	A South African financial intermediary (also known as broker) selling professional indemnity cover underwritten by insurance companies.
Never Events	These are specific clinical incidents and medical errors that should never occur. Examples include operating on the wrong side or the wrong patient. The concept of such events was first introduced by the National Quality Forum.
NHSLA	National Health Services Litigation Authority
Notification	Notifications refer to all incidents reported to indemnifiers by insured doctors. Doctors notify insurers either because they require assistance with a medico-legal enquiry or demand, or because they are concerned that the clinical care and/or outcome relating to a patient may result in a medico-legal enquiry or demand at a later stage. If they are on claims-made cover (see above), notification of circumstance is required to ensure protection for such event in future should this become necessary.
Notification date	Date on which an insured practitioner notifies an insurer of a case which requires/may require medico-legal cover.
NQF	National Quality Forum
Obstetrics	Obstetrics is the field of medical practice that is focused on pregnancy and childbirth.
Occurrence-based cover	A type of professional indemnity insurance where policyholders are protected against claims arising from incidents occurring during the policy period, irrespective of when such claim is made and including the time after a policy has been cancelled.
O&G	'Obstetrician and gynaecologist' refers to a registered specialty in South Africa that recognises doctors' post-graduate training and accreditation in the diagnosis, treatment and care of women's health.
Office of Health Standards Compliance	It is an independent body established in terms of the National Health Amendment Act of 2013 to ensure that both public and private health establishments in South Africa comply with the required health standards.

Office of the Health Ombud	This independent body established in terms of the Health Amendment Act of 2013 is located within the Office of Health Standards Compliance and is responsible for considering, investigating and disposing complaints from the public related to breaches of norms and standards of both public and private health care establishments.
OHSC	Office of Health Standards Compliance
OMRO	Outcome Measurement and Reporting Organization
Outcome Measurement and Reporting Organization	It is an independent, to-be-established platform for providers, patients and other stakeholders in the provision of health care to generate patient-centred and scientifically robust information on outcomes of health care, as recommended by the Competition Commissioner following the Health Market Inquiry.
Paid settlement	This refers to a settlement paid on behalf of an accused doctor to a plaintiff as a result of a court order or other dispute resolution mechanism. Whilst it implies that there are merits to a patient's claim, this is not necessarily the case.
PCNS	Practice Code Numbering System
Plaintiff	A plaintiff is the person who brings a legal action against the practitioner.
Post-partum hemorrhage	This is significant blood loss by the mother following childbirth.
PPH	Post-partum hemorrhage
Practice Code Numbering System	This is the system that generates the practice number allotted to a supplier of a relevant health service by an organization or body approved by the Council for Medical Schemes (CMS) for purposes of enabling third party payments.
Professional indemnity cover	This is a form of liability insurance that provides legal defence and settlement costs for claims arising from a practitioner's professional practice.
PRONE	Predicted Risk of New Event
RAF	Road Accident Fund
Road Accident Fund	The Road Accident Fund is a State insurance scheme funded through a levy on motor vehicle fuel. It provides insurance to all users of South African roads, specifically indemnity insurance to persons who cause an accident and personal injury and death insurance to victims of motor vehicle accidents. Liability incurred in relation to property damage like damage to vehicles and their content or buildings is excluded.
Salpingo-oophorectomy	This surgical procedure removes the ovaries and the tubes connecting the ovaries with the uterus.
SALRC	South African Law Reform Commission

SASSiT	South African Society of Surgeons in Training
SASOG	South African Society of Obstetrics and Gynaecology
SASUG	South African Society of Urgynaecology
SASUOG	South African Society for Ultrasound in Obstetrics and Gynaecology
Shoulder dystocia	This obstetric emergency is when after the delivery of the newborn's head, the baby's shoulder gets stuck above the mother's pubic bone. Complications for the baby include brachial plexus injury, fracture of the clavicle and cerebral palsy; the mother may experience vaginal or perineal tears, uterine rupture or post-partum bleeding.
South African Law Reform Commission	This body established by the South African Law Reform Commission Act 19 of 1973 conducts research to inform the development, improvement, modernization or reform of the law.
South African Society of Obstetrics and Gynaecology	A voluntary membership-based organization, representative of the discipline of obstetrics and gynaecology, that strives towards excellence and equity in women's health through promotion of excellence in clinical practice, training and research, maintenance of high ethical standards, continuous professional development and co-operation with other professional bodies with similar goals.
South African Society of Surgeons in Training	A body run by trainees, who strive to bring the greater surgical trainee community together through education, research and social activities and to serve as a voice for the surgeon in training.
Tubal ligation	During this surgical female sterilization procedure, the tubes between the ovaries and uterus are cut or tied off.
Urogynaecology	This refers to the management of pelvic floor disorders in females and includes management of disorders of the bladder and bowel, like incontinence, as well as prolapse of pelvic organs.
Wrongful birth	This is a legal term where parents missed an opportunity to terminate a pregnancy as a result of alleged medical negligence, typically where fetal abnormalities associated with severe disabilities and/or lethal conditions were not detected during pregnancy.

Reference Methodology

I have used the Harvard style of referencing for all parts of this dissertation, excepting for the Journal Manuscript. Vancouver reference style is used in the manuscript in accordance with the Instructions for Authors of the South African Medical Journal, the peer reviewed journal that I have selected.

Contents

Part A: Protocol

Contact details

Masters Candidate	**Bettina Taylor**, MBChB, Int Dip Res Eth
(Investigator)	9 Woodside Close
	Tamboerskloof, Cape Town, 8001
	bettinat@constantiagroup.co.za
	+27 (0)71 675 1174 (phone**)**
Supervisor	**Susan Cleary**, BA, MA, PhD
	Associate Professor
	Health Economics Unit
	School of Public Health and Family Medicine
	University of Cape Town
	Faculty of Health Sciences
	Anzio Rd, Observatory
	Susan.Cleary@uct.ac.za
	+27 (0)21 406 6755 (phone)

PART A: Index

Introduction

South Africa is facing a medico-legal storm that is threatening to paralyse many of the country's health care services. Based on data from the Department of Health, contingent liabilities for alleged medical negligence by State facilities have increased exponentially over recent years, having reached about ZAR98 billion in 2019 (Bateman 2019), up from R55 billion in July 2017 and R40 billion the previous year (D Bass [Medico-legal Head, Western Cape Department of Health] pers.comm., Nov 2017). Taking into consideration that the national budget allocated to health in 2016/2017 was R184.217 billion (Blecher et al. 2017), the devastating impact the current status quo may have on health care service delivery and the progressive achievement of universal coverage is self-evident. Where claims cannot be defended successfully, settlements in the form of monetary compensation are paid from local health care budgets, draining funds allocated towards the provision of essential services. Whilst government is focused on mobilizing additional funds to ensure that all people obtain the health services they need without suffering financial hardship when paying for these, its health budgets are being usurped by the legal profession and plaintiffs who claim to have suffered undue harm within State health care facilities.

Problem statement and justification for research

Most severely affected by the country's medico-legal trends are maternal and child health care services (Taylor et al. 2018). As per data presented by the Department of Health in July 2017, of the total monetary demands against the State, R38.8 billion relate to obstetric and gynaecological services, predominantly for reasons of alleged birth asphyxia with resultant cerebral palsy (which alone account for R36.6 billion of registered claims). The increase in claims, especially where potential settlements are high due to the severity of the disability and the duration of the disability across predicted life expectancy, has been hypothesized to have coincided with promulgation of the Road Accident Amendment Act 19 of 2005, which came into effect in August of 2008 and which capped claims for those who suffered harm on

South African roads (Howarth & Hallinan 2016, Oosthuizen & Carstens 2015, SALRC 2017). Whereas contingency-based law firms previously focused on high cost claims relating to motor vehicle accidents, their focus is said to have shifted to high cost claims as a result of alleged medical negligence, where potential pay-outs, and hence profits, are more lucrative. The pursuit of cases of alleged medical negligence by plaintiff attorneys that promise the most favourable economic returns for their practices has been described by Berkley (2004).

Contrary to the State, the total quantum of monetary demands made against private health care institutions and associated practitioners is unknown. It is nevertheless said that trends relating to frequency and quantum of claims have followed an upward pattern in the private sector. According to the Medical Protection Society (MPS), a long-standing provider of professional indemnity cover for doctors in South Africa, the value of claims increased on average by more than 14% per annum between 2009 and 2016. The estimated long-term average claim frequency for doctors in 2015 was around 27% higher than in 2009 (Howarth & Hallinan 2016). Most affected have been specialties at greatest risk of incurring extremely high cost claims on the basis of severe patient injury associated with long survival. Included in this group are obstetricians, neurosurgeons, neonatologists and orthopaedic surgeons performing spinal procedures. For these specialist groups, private indemnity fees have increased exponentially in recent years, with obstetricians' annual premiums for occurrence-based cover[1] with MPS increasing from R250 000 in 2013 to R950 000 in 2018 (J van Waart [SASOG President] pers.comm., Nov 2017). This translates to a 280% increase in premiums over a five-year period (see Appendix 1 for O&G premium escalations over a 10-year period). Given these trends, results of a recent survey commissioned by the South African Society of Obstetrics and Gynaecology (SASOG) are not unexpected. Of 201 respondents who currently practice obstetrics, 21% indicated that they would definitely be stopping obstetrics in the next five years; at the other end of the spectrum, only 12% were certain to still be delivering

[1] Occurrence-based cover is a type of insurance where policyholders are protected against claims arising from incidents occurring during the policy period, irrespective of when such claim is made and including the time after a policy has been cancelled. This contrasts with claims-made cover where protection is only offered for incidents reported to the insurer whilst premiums are being paid, i.e. it provides protection for incidents that both occur and are reported during the policy period, regardless of when a claim is received.

babies after the same time period. The median response to the question "how likely are you to stop obstetrics in the next five years?" was 75%, meaning that half the cohort was of the view that there was at least a 3 in 4 chance that they would stop this part of their practice within the given timeframe (J van Waart [SASOG President] pers.comm., Nov 2017). Cost of indemnity insurance, closely followed by fear of litigation were cited as the leading reasons. In a country that has prioritized the halving of infant and maternal mortality rates as part of the National Department of Health's 2015/6 – 2018/9 eight-point strategic plan, 'it is conceivable that soon even those willing to pay for private services may struggle to find access to high quality obstetric care for reasons of scarcity of qualified staff (similar to specialized pediatric neurosurgery which is no longer available in the private sector)' (Taylor et al. 2018, p.150).

To avert a national crisis, multidimensional solutions spanning across the legal and health care sectors are urgently needed. One of the key initiatives aimed at mitigating legal risks in relation to the current status quo is the research performed by the South African Law Reform Commission (SALRC)[2] with a view to recommending relevant legislative change. Focus areas include inter alia review of contingency-based litigation in the context of medico-legal claims, structured as opposed to once-off lump sum payments, as well as the need for prescribed guidelines for the calculation of damages (SALRC 2017).

From the perspective of health care service delivery, reasons for litigation must be addressed and predictors of litigation understood for purposes of guiding effective risk management interventions. Despite the looming calamity, data, however, remain scarce. In the private sector, MPS, who has been the dominant custodian of medico-legal information, has to date not been willing to share relevant clinical and actuarial data, despite requests from professional societies (A Taylor [President Neurosurgery Society] pers.comm., Nov 2017; J v Waart [SASOG President] pers.comm., Nov 2017) and legal academics (Coetzee &

[2] The South African Law Commission, established by the South African Law Reform Commission Act 19 of 1973, conducts research to inform the development, improvement, modernization or reform of the law. The enquiry into medico-legal claims follows a request from the Ministers of Health and Justice and Constitutional Development.

Carstens 2011). As a result, there is no published research in South Africa investigating factors associated with medico-legal suits against practitioners in the private sector, including associated trends. Without such information, patient safety and clinical risk management initiatives cannot be focused in a meaningful manner. Although data in the public sector also remain scarce, the national and provincial departments of health have commenced a collaborative process, which includes rudimentary data analysis. For example, the medico-legal burden across provinces, and including specifically for obstetric and gynaecological services, is being reported.

Literature review

Reasons for increased medical negligence claims in South Africa

The reasons for the increase in medical negligence claims in South Africa are complex and multi-factorial, ranging from patient-centered legislation enacted over the past two decades[3] with a parallel increase in awareness by patients of their rights encapsulated in the former, to changes in the doctor-patient relationship, failings in the health care system, as well as updated business models and practices of lawyers, including direct-to-consumer advertising (Pienaar 2016). In the public sector, the contribution of fraudulent claims is currently under investigation by forensic consortiums (Bateman 2019).

Regarding deteriorating quality of care as a relevant contributor to the medico-legal status quo, van den Heever (2019) believes preventable neurological injuries to children at birth in the public sector to be a reflection of sub-standard maternity services provided to pregnant mothers, with the failures 'matched by maternal mortality ratios at public facilities'. In 2017 the maternal mortality ratio in South Africa's public sector is quoted by him to have been 135 deaths for every 100 000 live births compared to an expected benchmark of around 42

[3] Rights of bodily integrity, dignity, privacy and access to health care, which commonly form the basis of infringement in medico-legal cases, are enshrined within the Constitution (Pienaar 2016). Patient autonomy and confidentiality of information is emphasized in the National Health Act 61 of 2003. A child's right to bodily integrity, as well as right to participate in decision-making in relation to its health is emphasized within the Children's Act 38 of 2005.

for peer countries. Such failure he believes to be a result of institutionalized mismanagement resulting from system-wide governance failures, quoting both the country's Health Ombudsman, and the Auditor General as having stated that the public health system is in crisis. In the private sector, MPS, based on in-house experiences and analyses, has not attributed the organization's worsening claims experience to deteriorating standards of care[4], but rather patient dissatisfaction and perceived lack of caring (Howarth 2015). Supportive data have, however, not been forthcoming. Given an increase in patient complaints over a number of years, the Health Professions Council of South Africa (HPCSA) has also warned about a 'decline in professionalism among health care practitioners' (Bateman 2011, Malherbe 2013). The fact that an increase in medical errors, if indeed contributory, is not necessarily a result of unsafe practices, or indeed negligent behavior, by individual doctors, but can be due to system failures has been highlighted by Reason (2000). 'Humans are fallible and errors are to be expected, even in the best organizations' (Reason 2000, p.768). To protect against these, 'system defences' that include barriers and safeguards are important. When these defences fail, adverse events occur. This would be particularly relevant in a system that is highly fragmented (like South Africa's private sector) (Taylor et al. 2018).

International context: Predictors of medico-legal complaints

South Africa is not the first country grappling with increases in medical negligence claims and associated consequences. In the United Kingdom, payments made in respect of medical negligence claims against National Health Service hospitals doubled in the period 2007/8 to 2012/13 (NHSLA 2013). In the United States, insurance premiums paid by some health care providers have increased disproportionately in relation to their income, leading to early retirement of doctors (Howard 2009, Rovit et al. 2007). In the same country, concerns have been expressed about the high percentage of physicians that have adopted defensive practices in response to the perceived threats of lawsuits. Defensive medicine can lead to

[4] Standards of care are here interpreted to mean clinical decision-making, technical skills and adherence to clinical guidelines and protocols, rather than other aspects of quality that include for example doctor accessibility, communication skills and empathy which impact patients' perceived experiences.

unnecessary procedures that expose patients to needless risks and/or that incur unwarranted health care costs (Studdert et al. 2016, Roytowski et al. 2014).

To minimize litigation and its undesired effects, researchers have taken an interest in exploring claims- and physician-related factors that may be predictive of malpractice claims. Parameters investigated range from demographic factors like practitioners' age, gender and practice location, specialty-type, years in practice, patient volume and training, to error and procedure type (McGrory et al. 2009, Sloan et al. 1989, Rodriguez et al. 2008, Waters et al. 2003, Kravitz et al. 1991). Dependent on study objectives, doctor and claim attributes have been studied within physician organizations, insurance funds, governments and specialty groups. It is hypothesized that identification of predictors of medical malpractice risk may guide further research that will lead to the development and implementation of focused risk management interventions.

One of the challenges posed in identifying determinants of being sued for monetary compensation is the fact that in absolute terms, the number of claims against doctors – as opposed to total quantum of claims – is low (Rodriguez et al. 2008). As such, large datasets are useful. In the USA, the National Practitioner Data Bank (NPDB) requires any organization making a payment on behalf of a practitioner to report malpractice settlements (Waters et al. 2003). Where datasets are limited, use of proxies has to be considered. To this end, number of formal complaints against a doctor has been studied as potential predictor of summonses issued against practitioners. Whilst Rodriguez et al. (2008) demonstrated that across practice type high-risk specialists had a lower patient complaint rate but a higher lawsuit rate compared to primary care physicians, Hickson et al. (1994) concluded that obstetricians 'who have been sued frequently are more often the objects of complaints about the interpersonal care they provide even by their patients who do not sue'. Data suggests that within specialty groups, number of complaints may be a reasonable proxy for risk of litigation against any individual practitioner.

Managing medico-legal risks: Patient safety and quality of care initiatives

Litigation may be the result of many factors, including inadequate care received, poor communication and limited doctor access (Stimson et al. 2017). Disregarding vexatious and frivolous claims brought by vindictive and/or opportunistic patients and their lawyers, claims represent patient dissatisfaction. Irrespective of whether there was negligence or not, patient complaints – with or without associated demands for monetary compensation – are an indicator of perceived poor quality of care. Understanding and addressing physician- and care-related factors that may be predictive of malpractice claims is thus not only important from perspectives of stemming the malpractice tide and its adverse consequences, but also from perspectives of enhancing quality of patient care and a patient's care experience. To minimize litigation and its financial implications and favorably impact care delivery, the Department of Neurosurgery at the University of California has been strategically integrating risk management data in quality improvement initiatives (McLaughlin et al. 2016). Prompted by the litigation crisis, the obstetric patient safety program implemented by the Hospital Corporation of America (HCA), the largest private health care delivery system in the United States, has resulted in improved patient outcomes, a lower Caesarian section rate and reduced claims (Clark et al. 2008). Whilst some risk predictors like medical school attended may raise more questions than answers in the short-term, others, like procedures associated with medico-legal complaints, can assist in the prioritization of risk interventions (Waters et al. 2003).

Study Objectives

The objective of the study is to explore medico-legal data and trends relating to obstetricians and gynaecologists (O&G's) in South Africa's private sector, with the specific aim

1. to calculate annual incidence of medico-legal cases amongst this practitioner group and describe historic trends in this regard,
2. to estimate the contribution of pregnancy-related cases (obstetric cases) to total number of medico-legal investigations and complaints,
3. to identify, analyse and describe clinical circumstances of previously settled claims,

4. to calculate and describe average annual incidence of medico-legal cases across individual private sector O&Gs and the contribution of individual practitioners to total number of medico-legal cases.

Methodology

Study design

This is a retrospective, observational study of medico-legal cases against O&G's in South Africa's private sector.

Study population

O&G's in private practice who have applied for insurance, are currently insured and/or were previously insured by Constantia Insurance Company in relation to their professional indemnity needs.

Data source

Medico-legal complaints were sourced from the claims database of Constantia Insurance Company. Constantia is a provider of professional indemnity cover in South Africa and holds private sector-related claims data on 521 O&Gs, most of whom are active policyholders. This is estimated to represent claims histories of more than two-thirds of O&Gs offering services in the private sector. Based on a recent study by Wishnia J. et al (2019) investigating the supply of and need for specialists in South Africa, there are currently 579 O&Gs practicing exclusively in the private sector, with another 190 State-employed O&Gs offering their services on a part-time basis to private patients (n_{total}=769). Medico-legal incidents stored in the database include the following:

- Historic medico-legal cases of policyholders and/or policy applicants who were previously insured by predominantly the Medical Protection Society (MPS) or via Natmed Brokers
- Cases registered with Constantia from date of policy inception with Constantia

The insurer furthermore holds doctor demographic data on file, obtained during the insurance application process and updated and verified from publicly available data sources, where relevant. For example, HPCSA registration status and place of qualification is checked against data published by the HPCSA. Where missing, practice location is taken from health care provider directories. Data fields updated and maintained during such processes include ID number; gender; specialist and sub-specialist type; qualifications, including date and university where degree was obtained; province of practice; year of entering private practice.

As date of first entering private practice as a specialist is poorly populated in the Constantia database, permission was requested from and granted by the Board of Healthcare Funders (BHF) to access data on their Practice Code Numbering System (PCNS) which is used by medical scheme administrators, managed care organizations and other service providers to pay doctor-related accounts. When doctors enter private practice, they have to apply for a practice number in order to be reimbursed by third-party payors.

Measurements

For purposes of analysis, all medico-legal cases on file and included in the research database were dated and categorized in terms of case type and clinical parameters. Practitioner-related demographic data were also captured and annual case frequency calculated per practitioner.

Case date

- *Notification date*: Year doctor became aware of case and/or notified the insurer of the case
- *Incident date*: Year in which an incident relating to a case occurred

Legal status of case (see Appendix 2)

- *Case type*: Most recent legal status relating to an incident[5].

  All cases were reviewed and case types defined, taking into consideration previous insurers' case type classification and updates from the practitioner shared during underwriting and claims management processes at Constantia. Depending on the insurer at the time of notification, these included notification of circumstance[6]; advice; assistance; assistance, claim or potential claim; request for records; PAIA RAF; OHSC complaints; regulatory matter; written complaint; HPCSA complaint; regulatory matter; claim or potential claim; subpoena; inquest; letter of demand; summons; unknown.
- *Case category*: Taking into consideration case type, as well as financial data and general information captured at the insurer, cases were assigned to broad medico-legal categories to enable analysis of settled claims, as well as the different manifestation types of patient dissatisfaction, ranging from financial demands and complaints via the regulatory and legal systems, to legal enquiries into care received to written complaints without the involvement of lawyers. For each category, cases were coded as '0' or '1' to indicate whether criteria for the group were met ('0' = no; '1' = yes).

Clinical context of a case (see Appendix 3)

- *Third-party involvement*: This was focused on identifying complaints that were leveled primarily against another third party and/or where there was documentation of significant error in relation to a third party
- *Case etiology*: This was the main identifiable factor driving a complaint, based on available evidence and as adjudicated by the researcher. Wherever possible, the underlying allegation of error or unethical behavior, actual clinical management error or

[5] Case types may change over time. For example, a notification may subsequently result in a HPCSA complaint or a request for records may be followed by a summons.

[6] Where doctors are insured on a claims-based basis, they have to - as soon as reasonably possible - inform their insurer of unexpected adverse outcomes and/or where errors are known to have occurred if they want to ensure future insurance cover should legal and financial support be required. There is a tendency by some practitioners to report any sub-optimal clinical outcome, irrespective of causality, to manage any potential financial exposure. Only a few notifications of circumstance progress to medico-legal investigations and complaints.

care-related complication was identified. Where available information did not allow identification of these, a case could be defined in terms of the clinical circumstance or unexpected poor outcome reported.

- *Injury site*: Where an iatrogenic injury to internal organs and vessels was documented, the site of injury was noted.
- *Procedure-type*: Where a case was related to a specific procedure, such procedure was classified.
- *Clinical circumstance*: Where relevant for data exploration, the diagnosis linked to a clinical circumstance was classified.
- *'Pregnancy-related' versus 'non-pregnancy-related' case*: As the definitions of obstetrics differ between clinicians and insurers, and because the gestational stage related to a pregnancy-related case was not always available, this measure was chosen as an alternative to 'obstetrics' versus 'gynaecology'. Pregnancy-related cases included all cases related to antenatal, peripartum and postnatal care, as well as early miscarriages, terminations of pregnancy and ectopic pregnancies. Where tubal ligation occurred/was planned during Caesarian section, the case was classified as pregnancy-related.
- *Device/equipment/medication-related case*: Where it was known that a medication or device was central to a complaint, this was marked in the database.
- *Clinical outcome*: Where there was evidence of death and/or severe neurological injury in the fetus/neonate and/or mother, this was captured. Other outcomes like loss of pregnancy and hysterectomy were also identified during exploratory analyses.
- *Cerebral palsy due to birth hypoxia/injury*: Cases with high probability of cerebral palsy due to birth hypoxia/injury were identified on the basis of the following - documented reference to CP/severe neurological injury other than an Erb's palsy with evidence of neglect and/or allegations of neglect and/or no associated documented causes to suggest that other factors led to a poor outcome (for example, admission for kernicterus in the context of an uncomplicated delivery with the birth of a healthy baby with good APGARS) or evidence of error/sub-optimal care during the delivery and low APGARS necessitating NICU admission.

Practitioner demographics (see Appendix 4)

- *Age*
- *Gender*
- *Province of practice*
- *Year of specialist registration*
- *Year of entry into private sector as a specialist*: Where the date fell prior to date of specialist registration[7], or where no date was available against a practice number[8], year of registering a private practice number was assumed to be year of specialist registration, with active practice and risk exposure starting the year thereafter.

Study limitations

Notification of cases is not classified in a standard manner across the industry. The manner in which the various insurers report on cases may also differ. As such, the researcher had to re-classify each notification on the basis of best available evidence to correct for heterogeneous reporting methods.

For many of the variables, for example incident year, but also all the clinical parameters, data sets were incomplete. The highly variable availability of clinical details of a medico-legal incident did not allow meaningful analyses across all cases (more than 2000) for single indicators like event, clinical circumstance, outcome, but rather called for sub-group analyses of indicators where there was certainty around an incident. For example, 'death' was a clear outcome measure and was highly likely to be captured due to the severity and doctor's awareness of the outcome. However, where there was evidence that a practitioner had caused iatrogenic harm like perforation of a bowel during surgery and the patient did not demise, the incident was certain, yet the patient outcome (for example, full rapid

[7] This may occur where a practitioner worked in the private sector as a general practitioner prior to returning to State for purposes of specialist training.

[8] Some practitioners register as part of a group practice. In these instances, date of first registration of a practice cannot be linked back to an individual practitioner.

recovery or prolonged hospitalization with repeat surgeries) could not be assessed in many instances.

It was furthermore not possible to adjudicate whether a practitioner failed to meet a reasonable expected standard of care. An adverse outcome or a patient complaint does not equal substandard care. The actual nature of a patient's complaint was also not necessarily the same as 'the event'. By means of example, the 'event' may have been perforation of a bowel, yet the patient's complaint could be focused on not having been informed that this could happen and if the patient had known, she would have chosen a different clinical management path.

It is furthermore acknowledged that the study is based on real life data, which may include data inaccuracies and gaps, like insurers' not capturing all the required information accurately or practitioners not declaring all relevant events. Every practical effort to correct these was made.

Analysis

Data management

For purposes of coding and analysis, two databases were constructed, with the primary database being case-driven. For all O&G s on file at the insurer, case histories were collated, including cases notified to previous insurers, cases not covered by insurance, as well as those reported to Constantia for assistance. Each case was allocated a unique identifier and linked to associated O&G's unique identifiers (MP registration number, ID number, policy number, together with a research-linked unique identifier that allowed anonymity of the dataset) together with the practitioner's demographic information. As case-related information is received in the form of e-mail communications plus/minus attached files, a manual process had to be followed to capture this in a summarized format into data fields for ease of review and classification. For each case, the previous insurer's summary and/or the practitioner's notes on a case were entered in separate data fields. Similarly, year of incident and

notification of cases, as well as known financial data were captured. Once completed, each case was reviewed and coded in terms of the measurements described. See Appendix 5 for an outline of the data structures. Some cells were only populated for specific sub-groups.

The practitioner-driven database was derived from the case-based database using Python script (see Appendix 6). Similarly, a report was constructed that summarized risk exposure over time (number of doctors in private practice per annum, starting with year of first registered claim) and which was used as a basis for case incidence trend analyses.

To avoid potential duplication of a case and undue linking of a case to a practitioner in the context of an analysis focused on patient safety, the following notifications were excluded from the dataset for the final analysis:

- State-related incidents, given the objective of assessing private sector risks
- Request for records in terms of claims against the Road Accident Fund (RAF)
- Request for records and claims where there was evidence that these were directed at third parties other than the State or RAF

Statistical analysis

Statistical analyses were guided by multiple exploratory analyses. Descriptive analyses were generated in Excel, Microsoft Office 365 ProPlus.

Ethics and Communication

Ethics

Given the impending maternal health care crisis in South Africa as a result of obstetricians discontinuing practice for reasons of unaffordable professional indemnity fees, as well as fear of litigation, there is an urgent need to identify predictors of medico-legal claims against O&G's. Without such understanding, the focused development of policy interventions to avert this public health disaster is hampered. Whereas in the public sector birth injuries

have been shown to be the driver of claims, there are no documented studies in the private sector analyzing trends in O&G-related claims, including their etiology.

From perspectives of potential risks, maintaining anonymity of individual policyholder/policy applicant in relation to claims data is key. Divulging claims data linked to individual doctors without their consent could cause unnecessary reputational damage and impact the viability of a private practice negatively. Whilst the researcher, as permanent employee of Constantia Insurance Company, has access to all demographic data of policy applicants, as well as details of associated claims, confidentiality of individual policyholder information is maintained at all times, as mandated by the researcher's employment contract with the company (see Appendix 7 for employee contract). In conducting this study, permission to use company data was obtained from the employer (see Appendix 8). The original proposal was also shared with the President of the BetterObs Programme (SASOG) for comment. Individual practitioner's information was furthermore protected as part of this research. Where research data was extracted from the insurer's database, related practitioner information was de-identified. As no individual policyholder information linked to claims will be identifiable in the presentation of study results – given that data will be presented at an aggregated level – consent from individual policyholders for purposes of conducting this research was not sought.

Approval to conduct the research in its proposed form was obtained from the Health Sciences Research Ethics Committee, University of Cape Town.

Stakeholders

Other than Constantia Insurance Company who is the provider of the claims database, the primary stakeholder in this study is SASOG and its membership, as well as non-member O&Gs. Other key stakeholders include Department of Health (DoH), the South African Law Reform Commission (SALRC), Colleges of Medicine of South Africa (CMSA), Health Professions Council of South Africa (HPCSA), Council for Medical Schemes (CMS) and Board

of Healthcare Funders (BHF).

Reporting

Research findings will be shared with all the primary stakeholders in this study. A policy brief that includes the research findings will also be included as part of this dissertation. It is furthermore the intention of the researcher to publish findings in a publicly accessible format to assist with the development of risk management interventions aimed at curtailing the high litigation risk faced by O&G's in South Africa's private sector. Relevant research findings will be brought to the attention of the HPCSA and CMSA, as well as CMS and BHF, if appropriate.

Logistics

Copies of the databases, which are password-protected, are saved on the Constantia Sharepoint Portal which is backed-up on a regular basis. Where information was shared with external parties for purposes of deriving a practitioner-based database from the case-driven worksheet, it was anonymized.

Risks

The risks in relation to this public health research are deemed to be low. With data transferred between the researcher and external third parties having been de-identified, private information of individual doctors was protected.

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Appendix 1

MPS premium escalation over a 10-year period

Data was collated from market intelligence data, including contributions from HealthMan, a health care consultancy providing services to SASOG.

	O&G	Gynaecology
2009	R 109 240	R 56 940
2010	R 130 540	R 68 045
2011	R 187 830	R 101 030
2012	R 220 700	R 111 130
2013	R 254230	R 111 240
2014	R 330 000	R 131 080
2015	R 450 000	R 142 860
2016	R 650 000	R 163 860
2017	R850 000	R174 670
2018	R 925 000	R 203 220
2019	R 1 150 000	R 220 000

Table A1. Annual premiums by the Medical Protection Society from 2009 to 2019 for obstetricians and gynaecologists and those practicing gynaecology only

Appendix 2

Legal status of cases

Notification
Advice
Assistance
Assistance, claim or potential claim
Claim or potential claim
Claim
Complaint
Inquest
Letter of demand
Regulatory matter
Request for records
Unknown

Table A2. List of case types

Category	Definition	Description
5	Paid settlements	This includes all cases where the plaintiff was compensated financially.
4	Monetary demands	This includes all 'claims', 'letters of demand' and 'potential claims' with evidence of high associated defence costs and/or estimated settlement costs
3	Formal demand/complaint via the legal or regulatory system	This includes all cases where there is evidence of a dissatisfied patient who has lodged a complaint via the legal or regulatory system. In addition to monetary demands, it includes HPCSA and OHSC complaints (regulatory matters).
2	Engagement of the legal	These are cases where there is evidence of a

	or regulatory system	dissatisfied patient who has initiated a medico-legal process, i.e. engaged the legal and/or regulatory system. In addition to category 3 cases, requests for records to pursue a potential claim against the practitioner are included here.
1	Patient dissatisfaction with or without engagement of the legal or regulatory system	These are all cases where there is evidence of a dissatisfied patient. Contrary to category 4, however, they are not necessarily associated with an active medico-legal investigation and/or the engagement of the legal and/or regulatory system. Written complaints and cases of 'assistance' or 'potential claims' where there is no evidence of legal costs incurred and/or estimated settlement costs and/or associated request for records are also included. Specifically excluded are notifications of circumstance where there is no documented proof of an adversarial patient.

Table A3. Definition and description of medico-legal case categories

Unique case ID	Case type	Category 5	Category 4	Category 3	Category 2	Category 1
1	Notification	0	0	0	0	0
2	Request for records	0	0	0	1	1
3	Settlement paid	1	1	1	1	1

Table A4. Demonstration of medico-legal case category coding ('0'=no; '1'=yes)

Appendix 3

Clinical categories

Anaethetist
Another O&G
General surgeon
Urologist
Paediatrician
Another medical practitioner
Hospital (private)
Pharmacy
State
Road Accident Fund
Class action
Employer

Table A5. List of third parties associated with cases

Doctor behavior, attitude, communication and/or billing practices
Medical aid issue, other than tariffs and codes
Patient confidentiality
Informed consent
Omission to provide patient care, advertently
Omission to provide patient care, inadvertently
Omission to provide patient care, unspecified
Delayed or incorrect diagnosis, gynaecological[9]
Delayed or incorrect diagnosis, maternal
Delayed or incorrect diagnosis, fetal

[9] Gynaecological refers to a non-pregnant patient.

Delayed or incorrect diagnosis, unspecified or other
Inappropriate management and/or choice of treatment, antenatal
Inappropriate management and/or choice of treatment, during labour
Inappropriate management and/or choice of treatment, postnatal
Inappropriate management and/or choice of treatment, gynaecological
Inappropriate management and/or choice of treatment, unspecified or other
Procedure-related complication, injury to internal organs/vessels
Procedure-related complication, post-operative complications and/or prolonged recovery
Procedure-related complication, retained surgical products
Procedure-related complication, surgical burns
Procedure-related complication, failed and/or inadequate procedure
Procedure-related complication, fetal harm
Procedure-related complication, wrong patient/wrong procedure/wrong side
Procedure-related complication, cosmetic outcome
Procedure-related complication, unspecified or other
Poor unexpected clinical outcome, adult
Poor unexpected clinical outcome, fetus/neonate
Poor unexpected clinical outcome, maternal and fetal
Clinical circumstance
Patient-related factor
Public liability incident
Unknown/multifactorial

Table A6. List of main identifiable etiological factors

Bladder
Blood vessel
Bowel
Ureter
Urethra

Uterus
Multiple organs/vessels/structures
Nerve
Other
Unknown

Table A7. List of injury sites associated with intraoperative injuries

Anesthetic, spinal/epidural
Anesthetic, general
Amniocentesis
Antenatal scan
Blood transfusion
Breast surgery
Cervical cerclage
Clinical examination
Drug prescription/administration
Delivery, unspecified
Delivery, caesarian section
Delivery, normal vaginal delivery
Dilatation and curettage
Endometrial ablation
Hysterectomy/oophorectomy/cystectomy/ myomectomy – surgical approach not specified
Hysterectomy/oophorectomy/cystectomy/ myomectomy – abdominal/vaginal
Hysterectomy/oophorectomy/cystectomy/ myomectomy – laparoscopic
Hysteroscopy
In vitro fertilization
Laparotomy
Procedure, unspecified or other
Special investigation, pathology

Special investigation, radiology
Special investigation, unspecified or other
Stem cell collection
Tubal ligation, open
Tubal ligation, laparoscopic
Tubal ligation/contraception, intra/transuterine

Table A8. List of procedures associated with cases

Appendicitis
Chorioamnionitis
Cord prolapse/cord around neck
Ectopic pregnancy
Intrauterine growth retardation
Malignancy
Maternal illness, unspecified or other
Meconium aspiration
Miscarriage
Placental abruption
Perineal tear
Post-partum hemorrhage
Pre-eclampsia/eclampsia
Premature rupture of membranes
Prematurity
Retained products of conception
Ruptured uterus
Sepsis
Shoulder dystocia

Table A9. List of diagnoses associated with cases

Conception/early pregnancy
Antenatal
Peripartum
Postpartum
Unknown

Table A10. Stage of pregnancy associated with pregnancy-related cases

Auvard speculum
Drugs
Diathermy
Essure
Filshie clip
Falloop rings
Gyrus
Heat pack
Implanon
Ligasure
Meshes and slings
Mirena
Novasure
Thermablate
Trochar
Ventouse
Verres needle

Table A11. List of devices, equipment and medicines associated with cases

Death, adult
Death, fetus/neonate
Death, maternal and fetal
Moderate to severe neurological deficit, adult
Moderate to severe neurological deficit, neonatal
Moderate to severe neurological deficit, maternal and neonatal
Death, patient; moderate to severe neurological deficit, neonate
Moderate to severe neurological deficit, maternal; fetal/neonatal death
Fetal abnormality
Infertility (includes hysterectomy post-partum)
Loss of pregnancy
Unplanned pregnancy
Chronic pain/symptoms
Other, including unspecified

Table A12. List of adverse clinical outcomes associated with cases

Appendix 4

Practitioner-related demographic data

Gender	Male
	Female
Age bands	<45 years
	45 – 54 years
	55 – 64 years
	=/> 65 years
Province of practice	Limpopo
	Mpumalanga
	North West
	Gauteng
	KwaZulu-Natal
	Free State
	Eastern Cape
	Northern Cape
	Western Cape

Table A13. Demographic categories and their respective variables linked to individual practitioners

Appendix 5

Case-driven database

Unique case identifier	Year of incident	Year of notification	Claim amount (R)	Settlement paid (R)	Defence costs paid (R)	Settlement estimate (R)	Defence cost estimate (R)	Case type (previous insurer)	Case type (researcher)	Case type category 5	Case type category 4	Case type category 3	Case type category 2	Case type category 1

…continued

Case summary (insurer)	Case summary (practitioner)	Third-party involvement	Case etiology	Pregnancy-related	Site of injury	Procedure type	Pregnancy stage	Clinical circumstance	Devices/equipment/drugs	Clinical outcome	Birth injury

…continued

Practitioner unique ID (research)	Practitioner surname	Practitioner name	Practitioner MP number	Practitioner policy number	Practitioner ID	Practitioner age (current)	Practitioner gender	Province of practice	Year of specialist registration	Year of entry: private practice

Table A14. List of data fields linked to individual cases

Appendix 6

Practitioner-based database

Unique practitioner ID (non-identifiable)	Age	Gender	Year of specialist registration	Year of entry: private practice	Province of practice	Years of risk exposure (calculated)	Count of cases for period of risk exposure from 2009 (category 5)	Count of cases for period of risk exposure from 2009 (category 4)	Count of cases for period of risk exposure from 2009 (category 3)	Count of cases for period of risk exposure from 2009 (category 2)	Count of cases for period of risk exposure from 2009 (category 1)

Table A15. List of data fields linked to individual practitioners

Appendix 7

Extract of researcher's employment contract with Constantia Insurance Company

14. PRESERVATION OF SECRECY

You will not reveal to any person, firm or corporation, any of the trade secrets or confidential operations, procedures of dealings or any information concerning the Company, functions, transactions or affairs of the Company or any details of the customers of the Company or their requirements or the services provided to them by the Company, and will not use or attempt to use any such information in any manner which may injure or cause loss either directly or indirectly to the Company. Any breach of the above will result in you becoming subject to the Company's disciplinary procedure.

Appendix 8

CONSTANTIA
Insurance Company

At:: University of Cape Town

13 July 2018

To whom it may concern

CONSENT TO USE DATA | CONSTANTIA INSURANCE COMPANY LIMITED

With reference to the above matter.

I, Dr Brad Beira have the required authorisation to act on behalf of Constantia Insurance Company Limited ("The Company").

The Company hereby consents to the use of its anonymised data for purposes of research aimed at understanding determinants of litigation in the South African private healthcare sector and which will form the basis of the below mentioned student's dissertation for her degree in Masters of Public Health.

STUDENT DETAILS:

FULL NAMES	: Bettina
SURNAME	: Taylor
STUDENT NUMBER	: SCHAND011
DEGREE	: Masters of Public Health (Health Economics)
DISSERTATION TITLE	: A retrospective, observational study of the determinants of medico-legal incidents amongst obstetricians and gynaecologists in the South African private sector

Yours faithfully

DR BRAD BEIRA

Signature Removed

EXECUTIVE: GOVERNANCE, RISK AND COMPLIANCE

Part B:
Structured Literature Review

PART B: Index

Objective

The literature review was aimed at identifying trends relating to medico-legal cases against obstetricians and gynaecologists (O&Gs) in South Africa's private sector, particularly in terms of incidence of claims and associated etiological factors, as well as factors that may be predictive of these. To this end other countries where O&Gs and their indemnifiers have experienced medico-legal challenges were identified, with a view to describing the clinical context within which medico-legal complaints have arisen for this specialist group elsewhere. This was not only important for purposes of guiding local exploratory analyses, but comparison of etiologies underpinning medico-legal complaints across different healthcare systems could potentially point to risk factors and their distribution that are peculiar to the South African private sector, as such warranting further investigation. The literature review was furthermore focused on the identification of potential risk mitigation strategies and their outcomes, where relevant. As the foundation of quality of care, training, education and professional oversight of O&Gs in South Africa was also evaluated. With the broader research project intended to support the primary prevention of medico-legal complaints and investigations and the design of strategies aimed at constantly improving patient safety, publications focused on secondary and tertiary risk management solutions like dispute resolution management and judicial reform were excluded from the review.

Search strategy and selection criteria

A broad search strategy was adopted. Searches on Pubmed and Google Scholar were supplemented with review of grey literature, where relevant.

The Pubmed search used the terms [("malpractice" OR "negligence" OR "indemnity") AND ("causes" OR "solutions" OR "risk management" OR "interventions")], with articles published between 2008 and 2018 considered for initial review. Important studies generated prior to those dates where identified and included in the literature review on the basis of having been quoted as key references within former. For the Google Scholar search, review of studies was guided by the relevance assigned by the engine following a search using the

terms “obstetric malpractice negligence review clinical risk management interventions solutions”.

The following criteria guided selection of articles for review of the abstract and/or full article:

English and German language

Original research and review articles focused on and/or including

- reasons for doctors being sued, especially obstetricians and gynaecologists;
- predictors/determinants of doctors being sued;
- classification systems underpinning medico-legal data analyses regarding determinants of claims
- early identification of ‘at risk’ doctors
- early identification of system failures
- interventions aimed at improving safety of health care delivery in the context of high medico-legal risk
- outcomes of patient safety improvement programmes

Articles with the following characteristics and/or focus areas were excluded:

- Foreign language, other than German
- Defensive medicine practices
- Dispute resolution mechanisms
- Judicial (tort) reform

International data

An increase in the frequency and quantum of claims relating to alleged medical negligence has been described in many parts of the world. Whereas the USA is known for its litigious climate, other countries have also reported a steady rise in reported cases of alleged medical negligence. Quam, Dingwall & Fenn (1988) reflected on fears that the increasing number and cost of claims in the UK may be indicative of the American medical malpractice crisis reaching British shores. Chen et al. (2012) indicated that the number of civil cases

against health care practitioners in Taiwan was four times higher in 2007 than in 2004. In Saudi Arabia, Samarkandi (2006) observed an increase of 26% in the number of medical negligence claims between 2001 and 2002. In their review of medical malpractice litigation in China from 1998 to 2011, Li H et al. (2014) refer to 'an unprecedented level' of disputes between patients and doctors. Across the globe, researchers have been prompted to analyse claims data as a result of these trends, with the intention of assessing the financial impact of increasing medico-legal risks, understanding the impact on practitioner well-being and practice patterns and using medico-legal data as a basis for patient safety improvement initiatives. Given that publications emanated from both developed, as well as developing countries, insights from heterogeneous environments with a broad spectrum of resources and different health care and legal systems could be gained.

The following framework guided the identification of predictors of medico-legal risk in these countries:

1. O&G specialty as a determinant of litigation (including trends in this regard, as well the separate contribution of obstetrics and gynaecology to this risk)
2. Clinical events, circumstances and outcomes associated with obstetric and gynecological medico-legal risks
3. Other predictors of claims, like for example practitioner behavior, previous complaints, place of practice and place of training

In reviewing claims data, variability in terms of reporting was taken into consideration. Whilst some studies report on paid claims only, the majority of studies include all claims, irrespective of final payment. Whereas an understanding of all claims is important, those associated with a paid settlement are most likely to reflect substandard care, despite the fact that some cases are settled without there being merit (Brennan, Sox & Burstin 1996).

Obstetrics and gynaecology as a determinant of claims and associated payments

From the perspective of an indemnifier, the specialty of obstetrics and gynaecology was consistently associated with an increased medico-legal risk amongst the various practitioner groups.

- In Saudi Arabia, 114 out of a total of 464 claims (24.6%) closed during 2008 and 2013 were related to O&G. 92/114 (80.7%) of these were related to obstetrics as opposed to gynaecology, with higher ruling in favour of plaintiff (61%) in former, as opposed to 18% in gynaecology (AlDakhil 2016).
- Of 7237 claims opened between 1986 and 2010 in Spain, 12% related to O&G, ranking O&G in second position among high-risk specialties after orthopaedics and trauma surgery (Gomez-Duran et al. 2013). Within the group of O&G, 61.9% of claims related to obstetrics.
- In the UK, obstetrics and gynaecology accounted for 10% and 5% respectively of clinical negligence claims received in 2016/2017 by the National Health System. Together these groups exceeded the otherwise highest claimant group, orthopaedic surgery. In terms of the value of clinical negligence claims, the specialty accounted for 52% of the total value of clinical claims received (obstetrics 50%, gynaecology 2%), with cases of cerebral palsy driving obstetric costs (Magro 2017).
- In China, obstetrics and gynaecology accounted for the highest percentage of claims lodged between 1998 and 2011 (162 of 841 claims) for any specialty, on par with orthopaedics at 19% (Li H et al. 2014).
- In a retrospective study of 636 cases of medical malpractice on file in the Forensic Medicine Association in Turkey – a statutory body providing expertise in medico-legal cases – the majority of cases related to O&G (107 cases which amounted to 16.8%). Of these, almost all were in the context of obstetrics (96%), with only 4% relating to gynaecology. In 31% of O&G cases (n=33), there was evidence of medical negligence. It is stated that 'none of the cases related to gynaecology were found to have an element of error' (Büken, Büken &Büken 2004).
- Based on 10 915 O&G claims from 20 insurance carriers obtained via the Physician Insurers' Association of America data-sharing project, Glaser, Alvi & Milad (2017) demonstrated that litigation claims for obstetrics and gynaecology procedures had higher average indemnity payments and higher paid-to-closed ratios[1] than other specialties. Although no figures were presented, it was stated that settlements related

[1] A claim is closed once a dispute resolution process has been completed. Subject to the outcome of such process and as influenced by the merits of the case, a settlement may be paid. A 'paid-to-closed' ratio indicates the proportion of closed claims that have an associated settlement payment.

most frequently to gynaecological surgery. The single largest indemnity payment over the time period was associated with an O&G surgical case (no further details provided).

- Of interest was also the study by Jena et al. (2011) who analysed malpractice data of almost 41 000 US-based physicians from 1991 through 2005 with 233 738 physician years of coverage. Whereas incidence of a malpractice claim was lower than for other specialties (~11% for obstetrics and gynaecology and 8% for gynaecology, compared with 19% for neurosurgery and cardiothoracic surgery), gynaecology appeared to be associated with the highest ratio of claim payment/any claim for any of the specialties (estimated at 36%)[2]. As such gynaecology was also associated with the third highest incidence of settled claims amongst the different specialist groups (exceeded marginally by general, cardiothoracic and orthopaedic surgery). For gynaecology the estimated incidence of a claim associated with a settlement was about 6% versus 5.5 % for obstetrics/gynaecology. In terms of pay-outs, median gynaecology-associated payments were $80 000, versus $150 000 for obstetrics and gynaecology. For the respective mean values, the relative difference was less, with mean pay-out in gynaecology being $270 000 and for obstetrics/gynaecology $350 00.

Irrespective of the nature of the health care system, O&G appears to be a driver of medical malpractice claims, especially with regards to obstetric care. Where reported, the frequency of obstetric claims was consistently higher than that of gynaecological claims. Lack of clear definition of obstetrics and gynaecology within the various studies made direct comparisons in terms of obstetrics versus gynaecology risks between countries difficult, however. Whereas the clinical definition of obstetrics focuses on care relating to pregnancy and chidbirth[3], insurance categories defined on the basis of specialty type and scope of practice vary. By means of example, Kravitz, Rolph & McGuigan (1991) listed cases of therapeutic abortions within their gynaecological as opposed to obstetric category, whereas Büken, Büken &Büken (2004) classified same as obstetric claims. Amongst South African indemnifiers, pregnancy-related care up to 24 weeks gestation is generally covered within the gynaecology insurance category. It is only when a fetus is deemed to be potentially

[2] The comparator figure for obstetrics and gynaecology was 27% (estimated).
[3] Merriam-Webster dictionary defines obstetrics as a 'branch of medical science that deals with pregnancy, childbirth, and the postpartum period'.

viable that pregnancy-related care is insured under the category of obstetrics which mandates significantly higher premiums. In Jena AB et al. (2011), the difference between O&G and gynaecology is not explained. Given that care in the South African private sector is often said to be modelled on health care service delivery in the US, the observation within American studies that cases relating to gynaecological surgery are commonly associated with settlements (as opposed to demands) is of interest.

Clinical events, outcomes and procedures associated with malpractice claims in obstetrics and gynaecology

To use claims data as a basis for focusing patient safety improvement initiatives, an understanding of the clinical situations that are most frequently associated with findings of negligence can be helpful. As there are, however, no standard classification systems for the analysis of clinical factors associated with claims, reporting of predictors of allegations of negligence varied widely across published studies. Major risk factors predictive of claims have been described in terms of clinical outcomes, clinical events and/or substandard care that may have been associated with these, including a combination of these. Key findings of the review are as such also reported in a heterogeneous manner.

Obstetric-related risks

Labour, delivery and the immediate post-partum period have been identified as high-risk in terms of potential medical error and litigation. In Gomez-Duran (2013), 53.5% of claims related to this part of the pregnancy cycle. In the review of 33 obstetric cases of proven negligence by Büken, Büken & Büken (2004), analysis of the case descriptions yielded a similar proportion. Given the nature of childbirth, a high incidence of claims around this period would be anticipated. Unexpected emergencies can readily arise during the birthing process, mandating a rapid and effective response by the medical team. Midwives, obstetricians, anaesthetists and members of hospital management must work closely together to ensure the safety of both the mother and the baby. Other than occurring with a high relative frequency, claims relating to the birthing process may be associated with high potential demands for damages as a result of injuries sustained, especially those resulting in cerebral palsy or brachial plexus injury of the newborn or maternal death (Clark et al. 2008).

Cerebral palsy (CP)

The fear of medico-legal litigation involving CP has been described as 'justifiably haunting modern obstetrics', with 73.6% of US obstetricians having faced litigation at some time, 'most often for alleged causation of fetal neurological impairment', and '60% of all obstetric malpractice insurance premiums covering birth management-related CP allegations' (Buttgieg 2016, para 1). Yet, according to the same author, medical negligence is proven in a mere 10% of CP court trials in the US, quoting scientific misconceptions about the condition and its causation as a key factor. Rather than being a single condition caused by severe hypoxia or ischaemia at birth, CP is a group of 'permanent disorders of the development of movement and posture, causing activity limitations that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain'. As per MacLennan, Thompson & Gecz (2015, p. 779), it is a highly heterogeneous condition 'with multiple causes; multiple clinical types; multiple patterns of neuropathology on brain imaging; multiple associated developmental pathologies such as intellectual disability, autism, epilepsy and visual impairment; and more recently multiple rare pathogenic genetic mutations'. Whereas the condition is commonly associated with allegations of birth hypoxia, 'epidemiological studies have shown that the origins of most CP are prior to birth' (MacLennan, Thompson & Gecz 2015, p. 779). Despite medical negligence being proven in a low percentage of cases in the US, CP litigation is continuing at a high rate (Buttgieg 2016). In the UK, the absolute number of CP cases litigated over a 10-year period up to 2016/2017 has remained static, with 213 new cases registered on average per annum. Demands have, however, escalated significantly, with some claims exceeding £20million. Possible explanations for this rise include 'increased life expectancy of children with CP, increased care costs, increased accommodation costs and the courts allowing for greater recoverability of certain heads of loss' (NHS Resolution 2017). Mean settlement costs in other parts of the world also exceed those of other cases. In Spain, the mean payment amount for a neurologically impaired child was €477 861. Contrary to the United States, however, 31.66% of cases resulted in a settlement (Gomez-Duran et al. 2013). In Saudi Arabia, 40% of birth hypoxia cases favoured the plaintiff, which accounted for 5.4% of obstetric claims and 3.5% of obstetric settlements (AlDakhil 2016). In Norway, 51% of cases (161/315) were awarded compensation for alleged birth asphyxia between 1994 and 2008 (Andreasen, Backe & Oian 2013). The difference in settlement rates between the US and

other countries may reflect different error rates in the delivery room, a variable litigious climate and/or a different interpretation of the condition by the judiciary and those who advise the judiciary. Where severe asphyxia due to malpractice around labour was confirmed in 177 infants in Sweden, Berglund et al. (2008) identified neglect to supervise fetal wellbeing in almost every case (98%).[4] Neglecting signs of fetal asphyxia was evident in more than two third of cases (71%).[5] Malpractice around the delivery was described in about half.[6] In Norway, the error review classification system aimed to differentiate between human and system error in proven cases of birth asphyxia. Human error was found to be the main factor in 89% of cases, with inadequate fetal monitoring being the most important factor, having been identified as the dominant mistake in half of the cases. This was followed by lack of clinical knowledge and skills, non-compliance with written guidelines, failure to consult a senior colleague and error in drug administration, typically failure in oxytocin administration (Andreasen, Backe & Oian 2013). Based on a review of 50 claims between 2012 and 2016 in the NHS, 'errors with fetal heart rate monitoring was the most common theme'. 'Inadequate staff training and monitoring of competency' was identified as another important issue, as was 'short-comings in informed consent' (Magro 2017, p.9).

Maternal morbidity and mortality

Not only poor fetal outcomes lead to litigation. Although Sakala, Yang & Corry (2013) in their review of the impact of the professional liability environment on maternity care in the US concluded that more claims are for newborn than maternal injury, they highlighted that this this did not reflect the incidence of maternal injuries suffered as a result of negligence, with childbearing women being about three times as likely to sustain negligent injury as newborns. In Turkey, 42% of obstetric claims relating to injuries that occurred as a result of negligence were associated with significant maternal morbidity and mortality, with or without associated fetal injury. In 9 cases, the mother died and in 5 the mother had a

[4] This included lack of or poor quality cardiotocography (CTG) recording, as well as no fetal blood sample despite a clear indication.

[5] This included delay of more than 45min from onset of pathological CTG to birth; increasing intravenous oxytocin infusion despite pathological CTG; hyperstimulation of uterine contractions

[6] Malpractice around delivery was defined as a more than 30minute delay from decision on delivery to birth, spontaneous vaginal delivery despite prolonged pathological or uninterpretable CTG recordings or traumatic instrumental delivery.

hysterectomy. Hemorrhage was the most common cause of death, most frequently as a result of uterine rupture. Uterine atony, retained placental fragments and placental detachment disorders were other reasons for bleeding and related poor outcomes. 1 fatality was associated with a perforated colon during laparoscopic intervention for an ectopic pregnancy and 1 with failure to diagnose eclampsia (Büken, Büken &Büken 2004). Significant maternal injury could furthermore be identified in 32% of obstetric claims reported from Saudi Arabia. Whereas haemorrhage leading to hysterectomy was the most common allegation, accounting for more than half of the claims associated with maternal injury, urinary bladder injury post Caesarean section was listed in 6/29 cases.

In Israel, infertility as a result of Asherman's syndrome was identified as an important cause of patient disputes following retained products of conception. Asherman's syndrome refers to intrauterine adhesions that typically occur as a result of trauma to the basal layer of the endometrium. Most cases follow termination of pregnancy using curettage, postpartum hemorrhage or delayed removal of retained products of conception (RPOC), with there being lack of consensus regarding the role of intrauterine infection in its etiology. In a series of 42 claims reported by Fejgin et al. (2014), 47% of cases were due to retained placental tissue following vaginal delivery and 19% following Caesarian section (Fejgin et al. 2014).

Shoulder dystocia

Based on the Royal College of Obstetricians and Gynaecologists clinical guideline (2012), shoulder dystocia is defined as 'vaginal cephalic delivery that requires additional obstetric manoeuvres to deliver the fetus after the head has delivered and gentle traction has failed'. Even where managed appropriately, it can be associated with significant perinatal morbidity and mortality. Maternal morbidity is increased predominantly for reasons of a higher incidence of postpartum haemorrhage (11%) as well as third and fourth-degree perineal tears (3.8%). For the fetus, brachial plexus injury (BPI) with potential permanent disability and birth hypoxia pose the major risks. For the birthing attendant the challenge when faced with a case of shoulder dystocia is 'to manage the problem as efficiently as possible to avoid hypoxic acidosis, and as carefully as possible to avoid unnecessary trauma' (Royal College of Obstetricians and Gynaecologists 2012, p.6). In the UK – based on figures from the National Health Services Litigation Authority (NHSLA) - neonatal BPI is the most common cause for litigation related to shoulder dystocia, with substandard care identified in about half of

cases. In Spain, the injury accounted for 27/548 or 4.9% of obstetric claims, with about one quarter of cases associated with successful litigation (Gomez-Duran et al. 2013). Similarly, low settlement rates (6/26 closed claims) were reported in the USA by Clark et al. (2008), with a finding that payment could have been avoided in half of the cases had there been complete and uniform record-keeping. This is in stark contrast to Saudi Arabia where 75% of settled obstetric claims related to BPI of the newborn, with settlement rates of 72% being reported in this context (AlDakhil 2016). According to Büken, Büken &Büken (2004), failure to diagnose an oversized infant prenatally and allowing birth to proceed naturally may contribute to poor outcomes.

Missed fetal anomaly

Wrongful birth is a legal term that refers to 'claims for clinical negligence where an opportunity has been lost to parents to terminate a pregnancy when this option would have been available if the impugned professional services had not been negligently performed' (Hassan, Chitty & Reardon 2014, p.312). Undetected fetal abnormalities associated with severe disabilities and/or lethal conditions form the usual basis of these claims. For obstetric cases settled in Turkey between 1990 and 2000, 4 related to failure to recognize congenital anomalies on ultrasound and 1 was as a failure to diagnose a congenital anomaly as a result of not observing a high alphafetoprotein (AFP) level on ultrasound, together accounting for 15% of obstetric claims[7] (Büken, Büken &Büken 2004). In Spain, erroneous ultrasound diagnosis was not only the commonest reason for a claim emanating from the antenatal period (47/548 or 8.6 % of O&G cases), but also the most expensive following cerebral palsy. Of note, however, is the low settlement rate at <20% (Gomez Duran et al. 2013). This contrasts with Saudi Arabia where no claims were made in this regard between 2008 and 2013. In the UK, less than 5% of number and value of claims relate to antenatal investigations, including fetal anomaly screening (NHS Litigation Authority, 2012). It has been postulated that the relatively low number of litigated cases over a 10-year reported period is likely to be as a result of published standards that all trusts in the UK must adhere to. These standards include guidance on training requirements, equipment to be used, pre-

[7] AFP is an important blood protein in early fetal life and can be used as an important sign of fetal health. It is used as a screening tool for Down's syndrome and can also predict other developmental disorders like spina bifida.

scan information for women, the content of the anomaly scan in terms of what should be examined, documentation and reporting, image capture and storage and the action taken should an anomaly be suspected (Hassan, Chitty & Reardon 2014).

Gynaecology-related risks

In their review aimed at understanding 'the anatomy of a claim' and 'how to avoid litigation' in gynaecology, Jha & Rowland (2014, p.53) contextualized the fact that other than for cancer patients, most gynaecological patients present with quality-of-life concerns. Where elective surgery is offered to address these, expectations are high and 'litigation is often related to whether these expectations have been met'. Based on an analysis of 504 gynaecological claims received by the NHSLA in the UK in 2012, the following key causes and injuries associated with patient demands were identified (the rest of the claims were categorized as 'other'):

		% of claims
Causes of claims	Wrong/failed/delayed diagnosis	22%
	Inappropriate/failed/delayed treatment	21%
	Intraoperative problems	20%
	Failure to obtain informed consent	6%
	Failure to recognize complication	4%
	Failure to perform operation/tests	4%
	Foreign body left in situ	3%
Injury underlying claims	Bladder damage/fistula	19%
	Unnecessary pain	16%
	Additional /unnecessary operation	13%
	Bowel damage/ dysfunction	6%
	Cancer	5%
	Psychiatric/psychological damage	4%
	Perforation	3%

Table B1. Key causes and injuries underlying gynaecology-related claims (source: NHS Litigation Authority, United Kingdom, 2012)

No details in terms of a coding hierarchy were provided, for example where bladder damage resulted in further surgery.

Specific procedures identified with regards to litigation risk were the following:

Sterilization

Although no mention of the relative frequencies of cases in the NHS were made by Jha & Rowland (2014), various grounds for medico-legal disputes were identified:

- Conception post-sterilization which could be as a result of a luteal phase pregnancy not identified at the time of sterilization, technical failure of the procedure or late recanalization of the fallopian tubes
- Performance of sterilization at time of caesarean section without the patient's consent or 'regret related to sterilization done at the time of C/S when the patient was consented immediately before the procedure'
- Inadvertent injury during the procedure such as bowel injury due to cautery

Where relative frequency of litigation relating to tubal ligation was reported, it accounted for 5% or less of all O&G cases (AlDakhil 2016; Gomez-Duran et al. 2013).

Whereas failed sterilizations resulting in the birth of a child can lead to claims for bringing up a child, only costs in addition to child maintenance, like for example medical care where a child is disabled, are generally granted by the courts (Jha & Rowland 2014).

Hysterectomy

In Spain, litigation relating to hysterectomies accounted for 9% (80/885) of O&G claims opened between 1986 and 2010 (with 16% of such cases (13/80) following C/S). Incontinence was cited as the most frequent complication (Gomez-Duran et al. 2013). Ureteric injury was the most common cause of litigation related to hysterectomies in the UK. Other than alleging negligence due to unintended internal organ injuries, patients questioned the legitimacy of the indication for surgery (Jha & Rowland 2014).

Colposcopy

Colposcopy is a procedure that allows visualization of the cervix, vulva and vagina for the early detection and treatment of pre-cancerous lesions. No figures in terms of frequency of claims could be identified during review of relevant publications. Physician (as opposed to lab errors) includes improper sampling, failure to obtain a complete history and incomplete follow-up (Jha & Rowland 2014).

Hysteroscopy

Hysteroscopy is an endoscopic procedure via the cervix to investigate and treat uterine pathologies. It was also used until recently for the insertion of Essure, a birth control implant that was withdrawn from the markets internationally following extensive reports of adverse events and associated litigation (McGinley 2018). Whereas none of the studies reviewed quantified the potential contribution of hysteroscopic procedures to overall claim burden, Jha &Rowland (2014) identified clinical negligence claims related to hysteroscopic procedures as uterine perforation and subsequent internal organ injury, with the most relevant risk posed by thermal injuries without subsequent laparoscopic investigation to exclude associated bowel injury.

Laparoscopic procedures

As for other surgical disciplines, laparoscopy has changed gynaecological practice over the past two decades. Based on the promise of less surgical trauma, shorter hospital stay, decreased post-operative pain and faster recovery, it has evolved from its use in diagnostic exploration and tubal ligation to becoming the preferred surgical route for the treatment of many non-oncological diseases (Shore, Lefebvre & Grantcharov 2015). Following a cross-sectional analysis of the 2005 Nationwide Inpatient Sample sponsored by the US Agency for Healthcare Research and Quality and which included data on 518 828 hysterectomies, Jacoby et al. (2009) found that 14% of hysterectomies were performed by the laparoscopic route, compared with 64% by the abdominal route and 22% vaginally. Whereas a Cochrane review confirmed speedier recovery following laparoscopic versus abdominal hysterectomy, this came at the cost of more urinary tract injuries (bladder, ureter) (OR 2.14). Compared with vaginal hysterectomy, no benefits of the laparoscopic approach could be demonstrated (with bleeding and operating time indeed increased) (Aarts 2009). For both laparoscopic

and vaginal hysterectomies, Mäkinen et al. (2001) demonstrated a significant learning curve. Surgeons who had performed >30 laparoscopic hysterectomies had a significantly lower incidence of ureter and bladder injuries (0.5 and 0.8% respectively) than those who had performed < or =30 operations (2.2 and 2.0% respectively). A decreasing trend of bowel complications was seen with increasing experience in vaginal hysterectomies (1.3% versus 0.3%).

Regarding studies reviewed to understand the different types of events and procedures associated with gynaecology-related claims, none specifically listed laparoscopic procedures (AlDakhil 2016; Gomez-Duran et al. 2013). This can be for reasons of inclusion in other broad categories (eg. hysterectomy). Alternatively, this type of surgical approach may not have been widely practiced in the regions during the analysis periods. Insights into claims related to laparoscopic gynaecological surgery could, however, be gleaned from studies in first world countries where new technologies are adopted more readily. Sandberg et al. (2017) analysed 133 laparoscopy- related gynaecology claims from the two largest liability mutual insurance companies covering 96% of Dutch hospitals over a 20-year period to gain insights into sub-standard care from a patient's point of view and to understand risk factors in relation to these claims. Visceral and vascular injuries were the driving reason for instituting legal action (accounting for 82% of the claims), especially bowel and ureteric injuries (40% and 20% respectively). More than a third of the injuries were entry-related (38%). Of note is the fact that more than three quarter of claims (77%) related to basic rather than advanced laparoscopic procedures like diagnostic laparoscopy, tubal ligations and salpingo-oophorectomies. The bowel injuries were not specific to any procedure, whereas 92% of the ureter injuries occurred during laparoscopic hysterectomy or adnexal surgery. Concerning the severity of the injuries, 78% of patients had to be re-operated at least once. A delay in diagnosis was a major contributor for a claim to be settled in terms of financial compensation. This typically occurred after thermal injuries. Four cases related to retained surgical items like needles, sheath of instrument and gauze. Overall, liability was accepted in 40% of cases. Findings amongst forty litigated cases of laparoscopic bowel injury between 1990 and 1998 in Canada were consistent with former, excepting a lower rate of accepted liability (with the litigation outcome favorable to the physician in 75% of cases) (Vilos 2002).

Urogynaecology

Urogynaecology refers to the management of pelvic floor disorders in females and includes management of disorders of the bladder and bowel, like incontinence, as well as prolapse of the pelvic organs (SASUG n.d.). With technological advancements, this branch of surgery has increasingly made use of commercially available meshes and slings to repair structural weaknesses of the female anatomy. In various parts of the world these have however become the subject of class action following overwhelming complaints of severe chronic pain and sexual dysfunction following their implantation (Knaus 2018). Whereas manufacturers have been central to these suits, doctors and regulatory authorities have also been intertwined in the 'mesh imbroglio' (Karlovsky 2016, p.1). The surgeon may be accused of poor technique and suboptimal informed consent and be found liable for the use of transvaginal mesh in various instances which may include knowingly using a mesh that is potentially harmful, especially if there is a conflict of interest due to a business relationship with the manufacturer; inadequate product knowledge, in particular with regards to research data, or lack thereof; inadequate surgical planning and/or expertise to use the device; failure to obtain adequate informed consent that includes sharing of relevant information including short- and long-term research data, personal experience with the product, product-related business interests, as well as standard surgical consent with the addition of mesh specific information such as potential future procedures that may be necessary to correct mesh complications and alternatives to mesh implantation and/or allowing the natural progression of the condition to take its course (Karlovsky 2016). Jha & Rowland (2013, p.55) have warned that with the first cases going to court in the US, 'this could well be a minefield waiting to explode'. In the UK, NICE has issued guidance on the use of meshes (Jha & Rowland 2013).

General risks

Like other procedure-based specialties, O&G is vulnerable in terms of 'Never Events', which represent a group of incidents in the delivery of health care services that are deemed unacceptable from perspectives of quality of care and as such should never occur. After initially being introduced by the National Quality Forum (NQF) as 'particularly shocking medical errors that should never occur', the term's use has expanded to signify adverse

events that are clearly identifiable and measurable, serious and usually preventable.[8] They are currently grouped into seven categories, including surgical or procedural, product or device, patient protection, care management, environmental, radiologic and criminal events (Agency for Healthcare Research and Quality 2019). Some of the specific events include the following:

Wrong site, wrong patient surgery

Based on an analysis of more than 27 000 physician self-reported adverse occurrences to an insurer between 2002 and 2008 by Stahel et al. (2010), 25 wrong-patient and 107 wrong-site procedures were identified. Significant harm, defined as long-term functional and/or structural damage, was inflicted in 43 patients (33%). One patient died. Whereas orthopaedic and general surgery was affected most commonly amongst the surgical disciplines, O&G was not immune. Medico-legally, these events tend to be indefensible. In the US, a Universal Protocol aimed at ensuring correct patient, correct site and correct procedure surgery was introduced in 2004 for all accredited facilities where procedures are performed on an in-patient or ambulatory basis (Stahel et al. 2010).

Unintended retention of a foreign object

Retained sponges and surgical instruments are a rare, yet persistent problem in surgical practice that can lead to major morbidity like reoperation for removal of the object, development of small bowel fistulae, obstruction and visceral perforations, as well as mortality. In their study investigating risk factors for this preventable error, Gawande et al. (2003) estimated that more than 1500 cases of a retained foreign product occur annually in the United States. This is despite stringent standards of the Association of Operating Room Nurses that stipulate that sponges must be counted once at the start and twice at the end of each procedure. Instruments must furthermore be counted for all surgeries that involve an open cavity. Whereas failure to perform counts was not identified as a significant risk factor on the basis of multivariate analyses in the research by Gawande et al. (2003), it was

[8] The National Quality Forum (NQF) is a US-based not-for-profit, nonpartisan, membership-based organization that works to catalyze improvements in health care. The evaluation and endorsement of evidence-based tools for standardised performance measurement is central to its efforts. Quality measures defined by NQF are used by the federal government, states and private sector organizations to guide quality improvement strategies (National Quality Forum).

noted as an important mechanism where procedures were performed on an emergency basis. Based on study findings, emergency procedures were noted as the most significant risk factor for retained foreign bodies, with unexpected change in surgery and increased body mass index being other predictors. Of note was also that following closure of an episiotomy or vaginal tears after delivery, sponge counts were omitted universally. Where counts were performed in the context of retained products, 88% involved a final count that was (erroneously) thought to be correct.

Intra-operative burns

Whilst the risk of burns acquired in the operating theatre is said to be low, injuries can be severe. In a claims review of surgical burns and operative fires in US hospitals by Choudhry et al. (2017), using data from an online legal research database, multiple etiologies of these types of intra-operative events were identified. In line with other studies, high-energy devices such as monopolar and bipolar electrocautery, lasers and ultrasonic energy systems were the most common cause, typically following their negligent placement or inadvertent pressure. Less common sources included chemical preparation solutions and use of heated fluids, as well as theatre devices and equipment like light sources. In a review of three cases of full-thickness burns acquired during surgery, Saaiq, Zaib & Ahmad (2012) identified faulty application of the grounding pad with inadequate patient contact as the underlying cause in all. Whereas most diathermy[9] machines are safe, the introduction of electrosurgical devices and surgical techniques that apply high levels of current to patients for extended periods of time has increased the risk of patient burns at the grounding pad site above the risk presented in 'traditional' electrosurgical procedures. Safety measures that have proven effective using traditional electrosurgical procedures may be insufficient to prevent grounding pad burns when used in procedures that require any combination of high current, long activation times and the use of conductive fluids for irrigation or distention (3M Healthcare 2007).

[9] A diathermy machine converts electricity of the main supply (240V; 50Hz) into high frequency current (>100 000Hz) to minimize the risk of electrical shocks. In monopolar mode, the current from the diathermy enters the patient through the active electrode and exits through the grounding pad. In bipolar mode, the current passes between the two prongs of the electrode without any significant flow through the patient. Electrocautery, which relies on the heat generated, has increasingly been employed in surgery for cutting and coagulation, ensuring effective haemostasis (Saaiq M et al. 2012).

Other

Other specific Never Events listed in the various categories include amongst multiple others intra-operative or immediately post-operative death in low-risk patients (American Society of Anaesthesiologists Class 1 patients), patient death or serious injury associated with a medication error or unsafe administration of blood, maternal death or serious injury associated with labour or delivery in a low-risk pregnancy while being cared for in a health care setting, death or serious injury of a neonate associated with labour or delivery in a low-risk pregnancy, patient death or serious injury resulting from failure to follow-up or communicate laboratory, pathology, or radiology test results or irretrievable loss of an irreplaceable biological specimen.

Other predictors of claims

Complaints history

The concentration of claims amongst a small group of practitioners has been described repeatedly. Studdert et al. (2016) in their analysis of 66 426 paid claims against 54 099 physicians in the US over a 10-year period concluded that, taking into consideration all 915 564 active physicians in the US, 1% of physicians accounted for 32% of all paid claims. The researchers also demonstrated the increased risk of another claim amongst repeat claimants versus risk of a claim amongst peers. Across all specialties and compared to practitioners with one previous paid claim, physicians who had two paid claims had almost double the risk of having another, whereas those with six or more paid claims had more than twelve times the risk of recurrence. The range of risk of a recurrent paid claim over a 5-year period across different specialties was furthermore highlighted, with O&Gs with one or more paid claims being at approximately double the risk of having another claim compared to internal medicine physicians (HR 1.89, 95% CI 1.58 – 2.25). Findings from an analysis of 725 paid claims from the Catalonia region in Spain between 2005 and 2014 were consistent, with only 3.2% of insured physicians having a paid claim against their name over a 10-year period and with risk of recurrence of a future paid claim almost doubled in those with two or more previous paid claims (Gomez-Duran et al. 2018). Indeed, not only paid claims have been shown to have predictive value. Based on their analysis of all medical malpractice claims closed in the State of Florida, US between 1975 and 1988, Bovbjerg & Petronis (1994, abstract) concluded that 'claims history had predictive value, even with only

unpaid claims'. Nevertheless, 'small paid claims were better predictors than unpaid claims, large paid claims were better predictors than small paid claims, and multiple paid claims were better predictors than single paid claims'. In Australia, Bismark et al. (2013) analysed a sample of all formal complaints filed against doctors over an 11-year period with the health service ombudsmen and found the distribution of complaints to be highly skewed, with 3% of Australia's medical workforce accounting for almost half of complaints, and 1% accounting for a quarter of complaints. There was a 'strong dose-response relationship with number of previous complaints' (Bismark et al. 2013, p.535). Whilst Entman et al. (1994) found no relationship between prior malpractice claims and the subsequent technical quality of obstetric care, this may be due to some practitioners having corrected their practice patterns. It also suggests that predisposing factors for patient dissatisfaction, other than technical ability, are associated with 'frequent flyer' doctors. Whereas all doctors may be prone to acts of substandard care, there is a clear difference in the manner in which their patients respond when adverse events have occurred. These are likely to be influenced by the practitioner's communication skills, attitude, levels of visible empathy and availability. There are furthermore environmental and system-related factors that may increase any individual practitioner's risk of complaints. The interplay of doctor- and system-related contributions to these is, however, complex (Spittal, Bismark & Studdert 2015). For example, disruptive behavior by a single individual can undermine the performance of the broader health care team; a doctor's receptionist can set a negative tone for the practice; a doctor overseeing deliveries in a labour ward where midwives are not trained adequately is at risk of poor patient outcomes in his or her practice. Whereas repetitive patient complaints do not necessarily reflect substandard care in terms of any individual doctor's technical performance, they may well be a powerful signal of other factors impacting patient care negatively.

Training

Various researchers have interrogated training- and competency-related aspects as potential predictors of medico-legal claims. In Canada, Tamblyn et al. (2007) concluded that scores achieved in the country's national licensing examination in patient-physician communication and clinical decision-making predicted complaints to medical regulatory authorities. Based on a study in Florida, Sloan et al. (1989) found physicians with relatively

prestigious academic credentials to have no better, and on some indicators, worse claims experience. The recent case of a South African professor of paediatric surgery demonstrates the high medico-legal risk key opinion leaders can pose (Karrim 2019). Of interest is also the finding by Waters, Lefevre & Budetti (2003) that there are differences in malpractice experience among medical schools. Where a medical school was identified as an outlier in terms of malpractice lawsuits prior to a practitioner's graduation, this was predictive of that physician's claims experience when entering practice. Hypotheses to explain why malpractice claims experience might relate to medical school attended included quality of education, training in interpersonal skills, predisposition of the school's graduates to enter specialties that might increase the frequency of malpractice lawsuits, types of students that the school attracts (selection bias) and institutional culture of medical schools.

South African data

Claims experience

Despite the ominous implications of current medico-legal trends for the future delivery of obstetric care, emergence of empirical data relating to causes, distribution and trends of O&G related malpractice claims has been slow, hampering efforts to focus effective and efficient risk management solutions. To obtain insights into factors within the health system that may have contributed to the exponential increases in professional indemnity fees for O&Gs in the private sector, various sources of information were interrogated.

Public sector

Within the public sector, the malpractice crisis is driven by the high number of claims for birth-related injuries. In 2017, 4063/7889 (52%) claims against the State related to O&G. Of these, 3089 (76%) were for cases of cerebral palsy, accounting for 94% of quantum of demands made in terms of O&G (or 64% of total demands) (D Bass [Medico-legal Head, Western Cape Department of Health] pers.comm., Nov 2017). Whilst it is unknown what proportion of such claims is fraudulent and/or opportunistic, those demands that do have merit are dominated by failure to monitor fetal distress. Based on a recent analysis by Frank & Buchmann (2019) of 200 public sector cases where intra-partum care was substandard, thus supporting the merit of a claim, failure to monitor fetal distress was evident in 43% of

cases. Failure to respond to fetal distress accounted for another 26% of cases, delay to Caesarian delivery for 13%, duration of the second stage of labour for 11%, prolonged active phase of labour 8% and not managing post-term pregnancy for 4%.

Medical Protection Society (MPS)

Although the O&G community has issued repeated calls for the sharing of clinical and actuarial data relating to malpractice claims in the private sector, key factors contributing to the exponential increases in professional indemnity fees by the organization in the last 10 years remain poorly documented. Whereas Howarth (2015) identified claims against O&Gs relating to wrongful birth and cerebral palsy secondary to birth hypoxia as the major cost drivers in the private sector, it remains unknown just how common such claims are, how their incidence may have changed, what their distribution is and to what extent they are settled for reasons of negligence by the doctor (as opposed to other parties). Where the Medical Protection Society (MPS) has previously shared figures in terms of trends, these have been generic in nature, with the following changes noted across the entire MPS membership (which included all specialist groups, family practitioners, allied health care professionals and State employees):

- increase in claims of 35% between 2011 and 2016 (Medical Protection Society 2018)
- increase in claim size by over 14% on average each year between 2009 and 2015 (Howarth & Hallinan 2016)
- increase of 27% in long-term average claim frequency between 2009 and 2015 (Howarth & Hallinan 2016)

Whilst recent reports provide some details that are specific to obstetrics, absolute numbers remain absent. No figures are furthermore available to assess previous quotes by the MPS that the worsening claims experience is more a reflection of patient dissatisfaction and perceived lack of caring than deteriorating standards of care (Howarth 2015).

The following is an integrated summary of 2018 and 2019 MPS reports to SASOG's medico-legal committee, based on claims over a 5year period (SASOG 2018, SASOG 2019):

GENERAL	
50% of O&G cases are deemed defendable, whereas the other 50% must be settled. No figures were provided in terms of how these percentages apply to obstetrics versus gynaecology claims, or across case types.	
OBSTETRICS	
Claim frequency distribution	*Cerebral palsy* 20% of claims (as per 2019 report)/30% of claims (as per 2018 report) *Missed chromosomal and structural fetal anomalies*[10] 8% of claims (as per 2019 report)/about 10% (as per 2018 report) *Tubal ligations* 8% of claims (as per 2019 report); this figures is interpreted as relating to tubal ligations after Caesarean section as the 2018 report estimates failed tubal ligations to be 'about 20% of claims – less if only Caesarean sections are counted' *Maternal and fetal morbidity* 49% of which – 25% relate to fetal morbidity such as stillbirth and fetal lacerations – 75% involve maternal morbidity including bowel and urinary tract injuries, fistulae, retained swabs, with 17% following maternal deaths resulting from haemorrhage and post-partum sepsis – 11% are as a result of shoulder dystocia
Settlement distribution	*Cerebral palsy* Accounts for 56% of settlements *Missed congenital and structural abnormalities* Account for 20% of settlements No information was provided on whether such percentages are based on

[10] It should be noted that missed fetal anomalies are insured within the gynaecology rather than obstetrics insurance category, which has historically allowed for indemnity cover of pregnancy-related care up to 24 weeks gestation.

	total quantum or frequency of payment.
Settlement amounts	*Cerebral palsy* R20 – R25 million/claim *Missed congenital and structural abnormalities (specifically missed aneuploidy)* R10 – R15 million/claim *Failed tubal ligation* R3 – R5 million/claim As these figures represent average values, they could have been influenced by major outliers, especially where datasets are small.
Timing of claims	Of the 20% of claims received > 3 years after the event, most are obstetric-related <50% of cerebral palsy claims are lodged within 3 years of birth; >20% occur after 10 years
GYNAECOLOGY	
Specific data remain outstanding. The 'most frequent claims remain laparoscopic surgery complications, followed by other surgical related complications such as bowel and urinary tract injury'.	

Table B2. 5-year claim analysis (adopted from MPS reports to SASOG, 2018, 2019)

HPCSA complaints

Other than the MPS, the Health Professions Council of South Africa (HPCSA) is a key custodian of medico-legal information that lends itself to trend analyses and identification of targets for quality improvement, both at the level of the individual doctor, as well as at systems level. As the body that guides and regulates the health profession in aspects pertaining to education and training, professional conduct and ethical behavior, the Council investigates complaints against practitioners registered within the ambit of the Health Professions Act, 1974 and ensures that appropriate disciplinary action is taken against such persons, where relevant, in order to protect the interests of the public. Two types of complaints that doctors may receive apply, depending on the perceived significance of the transgression by the Registrar's office and whether or not the matter falls under the

jurisdiction of the Council - a complaint from the Office of the Ombudsman, or a complaint from the Complaints Handling Unit and Investigations Office. Penalties imposed on those found guilty of unprofessional conduct range from cautions and reprimands to suspensions and monetary fines. Minor transgressions (defined as 'conduct which, in the opinion of the Registrar or Preliminary Committee of Inquiry, on the basis of the documents submitted to the Registrar or such committee, is unprofessional, but of a minor nature, and therefore does not warrant the holding of a formal professional conduct inquiry') are mediated by the Office of the HPCSA Ombudsman which was established in terms of Regulations Relating to the Conduct of Inquiries into alleged Unprofessional Conduct under the Health Professions Act, 1974 (Health Professions Council of South Africa).

According to the Annual Report 2017/2018, total number of complaints received by Council has remained static over a 4-year period, with 2597, 2944, 2755 and 2608 complaints listed for 2014/2015, 2015/2016, 2016/2017 and 2017/2018 respectively. Due to inconsistent reporting methodologies and limited detail, it was not possible to verify statements by the Acting CEO of the HPCSA in 2012 who referred to an increase in complaints as a result of a decline in the levels of professionalism among practitioners (Malherbe 2013). Indeed, since 2010/2011, no further increase in HPCSA complaints is evident (2903 complaints registered in that year). Although the breakdown of the type of offences investigated by the Committee of Professional Conduct Inquiry across all professional boards was of interest, it did not provide relevant insights in terms of reasons for claims amongst O&Gs. Whereas 70% of cases related to members of the Medical and Dental Board, no separate reports were issued in this regard, or indeed for specific practitioner types.[11] There was also no information regarding provincial distribution of complaints or complaints across the different sectors, private versus public.

Regarding cases mediated by the Office of the Ombudsman in 2017/2018, the majority of these complaints (n=798) related to fees, including accounts, billing and informed financial

[11] The Medical and Dental Council for medical and dental practitioners was extended fifteen years ago to a mega-organization of 12 professional boards that includes allied health care professionals like physiotherapists, medical technologists and dieticians. The current Medical and Dental Board, which oversees the conduct of family practitioners, specialists, dentists and medical scientists, is thus one of multiple professional boards governed by the Council.

consent (50.2%), followed by issues relating to medical reports (28%) and communications (21.8%) (HPCSA Annual Report 2017/2018).

In terms of allegations and findings relating specifically to technical aspects of quality of care, like allegations of incompetence, insufficient care/treatment and mismanagement of patients, negligence and misdiagnosis by practitioners, almost no details were provided. The only available information was via the Annual Publication of Judgements, which in 2018 listed matters relating to 28 practitioners (of unknown field of practice). Many of these matters related to over-billing and fraudulent bills and sick notes, rather than the clinical care provided by the practitioner. In comparing the number of the different type of offences reported between the 2010/2011 and 2017/2018 Annual Reports, no upward trend with regard to former parameters is evident over the 9-year period (with 2017/2018 being a potential outlier year).

TYPE OF OFFENCE	2009/2010	2010/2011	2015/2016	2016/2017	2017/2018
Incompetence	26	18	23	18	18
Insufficient Care/Treatment & Mismanagement of Patients	31	20	28	17	40
Negligence	15	23	23	15	33
Misdiagnosis	4	6	2	5	11
Total	76	67	76	55	102

Table B3. Type of offences as per matters finalized at inquiry level (partial extract from Annual Reports published by the HPCSA)

Regarding sanctions imposed, fewer practitioners appear to have been suspended in recent years, whilst erasures[12] seem fairly constant and cautions and reprimands have increased. Whereas 'Admission of Guilt' fines were not reported separately in the past, they have taken on a dominant role.

[12] Erasures are removals of practitioners' names from the HPCSA register for various reasons that range from failure to pay relevant fees to penalties following unprofessional conduct.

PENALTY	2008/2009	2009/2010	2010/2011	2015/2016	2016/2017	2017/2018
Suspension	45	47	27	28	10	12
Erasure	4	3	6	9	3	6
Fines imposed	71	64	67	45	23	39
Caution and Reprimand	6	9	14	23	31	20
Admission of Guilt Fine				118	95	160

Table B4. Penalties as per matters finalized at inquiry level (partial extract from Annual Reports published by the HPCSA)

Overall, information shared by the HPCSA was not helpful in understanding trends in patient complaints against specialists in the private sector. Given the challenges experienced by the HPCSA (see 'Professional Education and Training), this is unlikely to change in the short- to medium-term. In further support of such assessment is the fact that turnaround times for the finalization of complaints have increased from 76 days in 2014/2015 to 165 days in 2017/2018, which are indicative of severe operational resource constraints (HPCSA Annual Report 2017/2018). The trend in outcomes of matters finalised furthermore needs interrogation as there are suggestions that penalties in some instances have become too lenient, allowing practitioners who compromise patient safety to continue practising without the necessary interventions.

Office of Health Standards Compliance (OHSC) and the Health Ombud

The Office of the Health Ombud is an independent body established in terms of the National Health Amendment Act of 2013 and is located within the Office of Health Standards Compliance (OHSC, n.d.). It is responsible for considering, investigating and disposing complaints from the public related to breaches of norms and standards of both public and private health care establishments. Whereas the HPCSA Ombudsman mediates cases of minor transgressions by health care practitioners referred by the Registrar of the HPCSA, the Health Ombud investigates complaints and makes recommendations in relation to health establishments which includes persons employed by these. Contrary to determinations by the HPCSA Ombud which must be agreed by both parties, findings and recommendations by the Health Ombud are binding. No reports in terms of private sector investigations and complaints have been published since appointment of the first Health Ombud, who reports to and is accountable to the Minister of Health, in June 2016 (OHSC, n.d.).

Private sector hospital-related claims

Although O&Gs in South Africa's private sector typically run businesses independent of the facilities in which they practice, they rely on the support of hospital management, nursing staff and other medical professionals like anaethetists to ensure their patients' safety and optimal care. As such, information regarding trends in actual and alleged malpractice at private hospitals would be relevant as it is conceivable that medical malpractice claims against the former may increase as patients proceed with broad-based litigation as a result of harm suffered during hospitalisation. As for doctors, however, information relating to medico-legal actions against private hospitals is scarce. First results of a recent study investigating nursing malpractice in the private sector are thus of interest (Stellenbosch University 2018). Whilst no figures were published to support the statement by the authors that civil claims against private hospitals are 'skyrocketing' due to nursing malpractice, the findings are worthy of further interrogation. Of 122 closed claims against private hospitals (of which 74% were settled out of court), nursing malpractice was found to have significantly affected quality of life and length-of-hospital-stay of a large majority of plaintiffs, with '43% requiring additional surgery and 25% left with disabilities'. Factors underpinning suboptimal care included failure to follow guidelines in 91% of cases, lack of knowledge (75%), poor monitoring of patients (69%), failure to administer prescribed medication (66%), failure to respond to clinical signs (63%) and insufficient training (52%). As lead investigator of the study, Prof E. Stellenberg painted a 'bleak picture of nursing in private hospitals, with criticisms of inadequate attention to basic nursing care'. She also voiced her concern about substandard appointments in critical areas like theatres and the fact that 'care workers are performing the functions of nursing staff in many cases'. 87% of cases nevertheless involved registered staff nurses.

Responses to South Africa's medical malpractice crisis

To investigate medical liability reform policies and quality improvement strategies as a way of controlling litigation costs relating to medical errors, South Africa's government appointed the SA Law Reform Commission, as well as the World Health Organization (WHO), South Africa (SALRC 2017; Cardoso et al. 2017). Whereas a broad spectrum of solutions implemented abroad have been identified by these bodies, all have their roots in high-income countries. Initiatives to mitigate malpractice risks ranged from changes to the

medical litigation malpractice system like the introduction of specialised courts, alternative claims resolution mechanisms, caps on compensation and attorney fees and limitations on litigation, to alternative payment systems, no fault approaches, rapid resolution systems based on apology, as well as clinical safety programmes. Elements of latter programmes included clinical guidelines and standardised protocols, training, promotion of teamwork and reporting and analysis of adverse events to promote self-learning and constant improvement. Of particular note with regard to these type of quality-of-care improvement projects was the initiative by the Hospital Corporation of America (HCA), the largest private health care delivery system in the United States, as it not only resulted in improved patient outcomes and reduced claims, but it also lowered the Caesarian section rate[13] (Clark et al. 2008).

Modeled on former, the South African Society of Obstetricians and Gynaecologists (SASOG) has been proactive by launching the BetterObs programme in 2016, with the objective of promoting safe ante- and intrapartum care and, with that, also mitigating the risks of a successful lawsuit. Specifically in relation to optimizing clinical care, pillars of the programme include clinical protocols and guidelines, regular morbidity and mortality meetings at delivery facilities for purposes of self-audit and teaching and society-driven peer review to handle allegations of unprofessional conduct, repeated misconduct or members not following guidelines or protocols (South African Society of Obstetricians and Gynaecologists, n.d.). For its full benefits to be realized, however, it relies on the collaborative support of private hospital groups, other specialist colleagues like paediatricians, third-party payors and indemnifiers.

[13] High Caesarean section rates are amongst other reasons a reflection of defensive practice in a high-risk medico-legal environment. Where performed without a clear medical indication, they are said to add unnecessarily to health care costs.

Professional competence and conduct in South Africa: Oversight, key challenges and opportunities for improvement

With professional conduct and competence at the core of medico-legal investigations, it is important to outline the structures in South Africa that govern training and professional behavior of O&Gs and highlight some of the challenges and gaps identified.

For medical professionals to practice as specialists in South Africa, they must be registered in their relevant specialist category by the Health Professions Council of South Africa (HPCSA). Other than accrediting practitioners in terms of their professional competencies, the HPCSA guides and regulates medical education and training. It is supported in this role by the Colleges of Medicine (CMSA) and recognized academic institutions. The Colleges of Medicine (CMSA) is a non-profit company founded in 1954 by members of the medical profession. Whereas it is a criminal offence in terms of the Health Professions Act No.56 of 1974 to practice without a relevant license from the Council, College membership is voluntary. Historically, training programs for specialists have been diverse in terms of core syllabi and examinations. Since 2010, however, a more uniform approach has been adopted (HPCSA, Subcommittee for Postgraduate Education and Training, 2010). Registrars who commenced training on or after 1 January 2011 and who wish to register as specialists have to complete a defined national curriculum and pass national professional examinations, as well as a relevant research-based dissertation. Qualifying national examinations are conducted by the CMSA as the contracted National Examining Body of the HPCSA. A portfolio which is a certified record of in-service training also has to be maintained and signed-off by the departmental head of the registrar's training institution. For obstetrics and gynaecology, this includes a logbook of obstetric and gynaecological procedures performed by the candidate. To qualify as a specialist, a minimum number of cases per case type and as defined by the College must have been performed. Whereas doctors could in the past choose the route of a locally examined Master of Medicine (MMed), success in the exit examinations of the CMSA, together with completion of required training time in appropriate facilities, is now required to enable registration with the HPCSA as a specialist (The Colleges of Medicine of South Africa). Conditions for registration of specialists qualified in foreign countries are poorly defined (Mayosi et al. 2015).

As much as there have been positive developments in regulatory oversight of specialist training and registration in South Africa, gaps in the system that are designed to safeguard the public against inadequately qualified practitioners have been identified:

- Following an increasing number of complaints and repeated allegations of administrative irregularities, mismanagement and poor governance at the HPCSA, a Ministerial Task Team was appointed by the Minister of Health in 2015 to investigate these. Based on a structured process of investigation, the Task Team concluded that the HPCSA is in a state of 'multi-system organisational dysfunction which is resulting in the failure of the organisation to deliver effectively and efficiently on its primary objects and functions in terms of the Health Professions Act 56 of 1974', a situation described as a 'serious deficit in the health system'. Whilst various solutions to this have been proposed, including an overhaul of management, the Committee is of the view that the entire structure and organisation of the HPCSA requires review. Unbundling of the HPCSA into at least two entities has been suggested: the historic Medical and Dental Council, which constitutes a third of the current membership and which includes specialists like obstetricians and gynaecologists, and a Health and Rehabilitation Council for the rest of the professional membership. The 'deep systemic dysfunction' that has been identified has been seen to be a consequence of the extension of a single professional board (as the Medical and Dental Council for medical and dental practitioners) fifteen years ago to a mega-organization of 12 professional boards (Mayosi et al. 2015).

- Irregularities in the registration of foreign practitioners prior to 2012 have been reported (Khumalo 2012). Whereas the Council committed to re-auditing all the files of registered foreign doctors who have been practising in the country since early 2000, it is unknown to what extent such process was concluded with the necessary due diligence.

- A report by the South African Society of Surgeons in Training (SASSiT) has highlighted disparities in training across the eight medical schools in South Africa, with less than 60% of registrars agreeing with the statement that 'supervised surgical training at (their) institution is useful in preparation for independent practice' (Patel N et al. 2018).

Although curricula, exit examinations and registration have been centralised in the country, the responsibility for training continues to fall on the surgical department of each of the medical schools. Other than that training methodologies may differ at this level, varied access to for example specialised surgical units and equipment, as well as supervising consultants can impact quality of training. The high demand on registrars' time for service delivery in the context of general staff shortages and high patient loads is also compromising academic activities in the interests of patient care. Based on a study by Kruger & Veller (2014), 61% of surgical procedures performed by South African general surgical trainees are unsupervised. Abuse of Remunerated Work Outside of Public Service (RWOPS) privileges by at least some consultants has been highlighted as a potential contributor to inadequate teaching and supervision (Benatar 2014). To ensure adequacy of training facilities and support for post-graduate education and training, Benatar (2014, p.481) has called for an 'open investigation of the patient loads, surgical facilities and staffing levels of all training institutions, as well as of the thoroughness and accountability of the evaluation of practical experience, including scrutiny of well-prepared, validated case portfolios, before qualifying surgeons to enter practice as specialists'. Similarly, Patel et al. (2014, p.13) have recommended a review of the current model for general surgical training, given that there is doubt amongst registrars themselves that the 'level of training received currently is adequate to impart sufficient skills and acumen to practice independently upon qualification'. As part of this, they have suggested 'greater monitoring of the academic and service delivery responsibilities of consultants employed in the public and private sectors', as well as 'mentorship programmes for junior specialists'. The 'institution and enforcement of minimum provision and attendance requirements on academic activities' for trainees is furthermore proposed.

- Training in minimally invasive procedures was highlighted as a specific focus area that required improvement by the SASSiT survey. With only 37.1% (39/105) of registrars of the view that they receive adequate training in minimally invasive surgery (MIS), surgical registrars have recommended 'mandatory completion of courses in MIS as a prerequisite for qualification', together with creation of opportunities for registrars to rotate through well-established local MIS centres, including in private academic centres

(Patel et al. 2014, p.13). In this regard, South African trainees are not alone. Shore, Lefebvre & Grantcharov (2015) have highlighted how insufficient training in laparoscopy is also a major barrier for gynaecological surgeons trained in North America, indicating that many programme directors, as well as practitioners were dissatisfied with the adequacy of training to perform laparoscopy confidently. To address this, a standardised curriculum has been proposed that includes simulator training and standardized assessments prior to real-time operating room experience or board certification. Whilst rapid technological advancement is creating exciting opportunities for potential improvements in patient care, new technologies and surgical techniques are posing unique challenges in relation to training and credentialing and with that quality of patient care and medico-legal risks (Lee, Kilic & Phelps 2011). Whilst simulator-based training is not integrated into the current national curriculum for O&Gs, some universities and practitioners support completion of the Winner's programme which is a theoretical and practical training and credentialing programme for endoscopy in gynaecology, supported by the European Academy of Gynaecological Surgery (The Colleges of Medicine of South Africa; P Dalmeyer [Fertility Specialist] pers.comm., Nov 2017). The practitioner has to demonstrate sound camera navigation and eye-hand co-ordination abilities, as well as suturing abilities in a simulated environment prior to being able to proceed (Winner's Project).

- Based on a review of guidelines published by SASOG, training and skills assessment in terms of antenatal fetal abnormality scanning also appears to have gaps. Whilst ultrasound screening forms part of the core FCOG syllabus, SASUOG has recommended that indemnifiers only provide insurance cover for fetal scans where practitioners can demonstrate alternative skills assessments via the Fetal Medicine Foundation and other SASUOG-approved processes (South African Society for Ultrasound in Obstetrics and Gynaecology, n.d).

Identification of research gaps and needs

Lack of claims-related information is not only hindering an understanding of the causes of the sharp increase in professional indemnity fees for O&Gs in South Africa's private sector, but also the development and prioritization of focused risk management interventions (Kravitz, Rolph & McGuigan 1991). Despite requests for data by legal academics and health care practitioners since at least 2011, the Medical Protection Society, the dominant professional indemnifier of private specialists for many years, has resisted sharing of meaningful claims-related information. The rudimentary reporting of regulatory complaints against health care practitioners in South Africa by the HPCSA has furthermore proven unhelpful in terms of understanding trends and risk factors relating to patient dissatisfaction in high-risk professions like obstetrics and gynaecology. Such status quo is contrary to experiences in other parts of the world where medico-legal data has been made available to practitioners and risk managers via research opportunities and/or structured sharing of information by claim managers and regulatory authorities. For example, in the United States, all malpractice claims settled on behalf of US physicians can be accessed via the National Practitioner Data Bank (U.S Department of Health and Human Services) and professional societies have developed clinical guidelines on the basis of closed claims data (Pegalis & Bal 2012). In Saudi Arabia, claims-related research has been conducted on data generated by the country's centralised adjudication process of medico-legal claims (AlDakhil 2016). In Spain, the Professional Liability Department (PDL) of Barcelona's Official College of Physicians maintains its own claims database that allows risk identification (Gomez-Duran et al 2013; Gomez-Duran et al 2018). Of interest are furthermore initiatives in Australia, where analysis of complaints to regulatory authorities is used to explore risk factors for complaints with the aim of improving quality of care. Specifically, Spittal, Bismark & Studdert (2015) have used number and time intervals of previous complaints to regulatory authorities, together with complaint issue and doctor demographic data to estimate a PRONE (Predicted Risk of New Event) score which is aimed at predicting doctors' future risk of complaints. It is also intended to model thresholds for focused risk management interventions.

If South Africa is to reverse current medico-legal trends, structured review of medio-legal data is important so that patient safety and dissatisfaction 'hotspots' ranging from specific

clinical practices and interventions, to individual practitioners' behaviour and/or technical expertise, to places of practice or training can be identified for purposes of quality improvement programmes. As the first study in South Africa to analyse medicolegal case histories amongst private sector practitioners, this thesis seeks to fill current knowledge gaps with regard to steep increases in professional indemnity fees and mounting medicolegal fears amongst private sector O&Gs, with a view to identifying potential solutions aimed at reduction of medico-legal risk, protection of O&Gs in private practice and the sustainability of quality maternal care.

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Part C:
Journal manuscript

A retrospective, observational study of medico-legal cases against obstetricians and gynaecologists in South Africa's private sector

Bettina Taylor, Susan Cleary[1]

Affiliations [1] Health Economics Unit, University of Cape Town, Anzio Road, Observatory, Cape Town, South Africa

Corresponding Author B. Taylor

Email: bettinataylor2@icloud.com

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Conflict of Interest:

- Bettina Taylor is an employee of Constantia Insurance Company Limited

Abstract

Background: The viability of obstetric practice in the private sector has been threatened as a result of steep increases in professional indemnity fees over the past ten years. Despite this, empirical research investigating key etiological factors to target risk management interventions has been lacking.

Objectives: The objective of the study was to explore private practice medico-legal data linked to obstetricians and gynaecologists to identify factors in clinical practice associated with claims for purposes of guiding future research and risk management solutions.

Methods: This was a retrospective, observational study of private sector obstetricians and gynaecologists' medico-legal case histories. All incidents declared to a prominent local professional indemnity insurer were categorized in terms of medico-legal case type, as well as clinical parameters. To allow for risk-adjusted calculations of case incidence, year of entry into private practice was estimated for all practitioners.

Results: Steep increases in medico-legal investigations and demands were demonstrated for both obstetric- and gynaecology-related cases from about 2003 to 2012. Whereas total number of claims, regulatory complaints and requests for records were similar for obstetrics and gynaecology in recent years (accounting for 52% versus 48% of known cases respectively), a significantly greater percentage of demands and paid settlements related to gynaecology rather than obstetrics (58% and 76% versus 42% and 24% of cases respectively). In obstetrics, about half of all cases on record with a paid settlement were in the context of severe birth-related neurological injury of the unborn (n=9). In a review of notifications over a 10-year period, hospital and other system-related failures were cited as having partially or fully contributed to alleged cerebral palsy in a number of cases. Insufficient data limited meaningful quantification in this regard, however. For gynaecology, procedure-related complications accounted for 92% of settlements, of which at least 41% were for intra-operative injuries to internal organs and vessels. Laparoscopic procedures were associated most frequently, followed by vaginal and abdominal hysterectomies/oophorectomies and Caesarian sections.

203/458 (44%) of doctors had no HPCSA complaint, request for records, letter of demand or summons in the previous 10 years, whereas 8/458 (2%) had more than one of any of these on average per annum. 50/458 (10.9%) of O&Gs in private practice for more than two years accounted for 138/228 (60.5%) of demands.

Conclusion: The higher number of gynaecological demands and settlements in comparison to obstetric cases was unexpected and is contrary to international experiences and public sector findings, calling for more research to identify reasons for this. Other than further exploring surgical outcomes in private sector gynaecological patients, some aspects of surgical training and accreditation standards in gynaecology may need review. Surgical mentorship programmes may need consideration. Regarding birth-related injuries, the contribution of system failures needs quantification and further interrogation. The high contribution towards medico-legal burden by a small group of practitioners suggests a need for doctor-focused interventions, including strengthening of peer review and regulatory oversight.

Key words

Claim trends
Medical liability reform
Patient safety
Risk management
Obstetrics and gynaecology
Medical negligence

Introduction

Claims for alleged medical negligence are a cause for concern in many parts of the world. Whereas high frequency and escalating quantum of claims have typically been associated with first world countries like the United States and Australia,[1] similar patterns of claim increases have more recently also been described in less developed countries. In Taiwan, there has been a fourfold increase in civil claims against doctors between 2004 and 2007.[2] Li et al. refer to an 'unprecedented level' of disputes between patients and doctors in their review of medical malpractice litigation in China from 1998 to 2011.[3] In South Africa, contingent liabilities for alleged medical negligence by State facilities have increased exponentially over recent years from about ZAR56.96 billion in 2017 (D Bass [Medico-legal Head, Western Cape Department of Health] pers.comm., Nov 2017) to ZAR98 billion in 2019.[4] In the private sector, the Medical Protection Society (MPS), a UK-based indemnifier of medical specialists, reported an increase in claims of 35% between 2011 and 2016 and an increase in claim size by over 14% on average each year between 2009 and 2015 across its membership, which includes specialist groups, family practitioners, allied health care professionals and State employees.[5],[6] In both sectors, claims in relation to obstetrics have been identified as the predominant determinant of financial risk for indemnifiers. In 2017, 4063/7889 (52%) claims against the State related to obstetrics and gynaecology (O&G). Of these, 3089 (76%) were for cases of cerebral palsy, accounting at R36.633 billion for 94% of the demands made in terms of O&G (or 64% of total demands) (D Bass [Medico-legal Head, Western Cape Department of Health] pers.comm., Nov 2017). Whereas claims data are unavailable in the private sector, professional indemnity fees have risen most steeply for O&Gs. Over a 10-year period, rates for occurrence-based cover charged by the Medical Protection Society (MPS) have increased almost tenfold, from R109 240 in 2009 to R1 150 000 in 2019. This contrasts with premiums for practitioners whose practice is limited to gynaecology, including antenatal care up to about 24 weeks gestation, which have increased less than 4-fold over the same period. Whereas in 2009 O&Gs providing full obstetric services paid less than twice the amount of colleagues with a more limited practice (C Venter [Director, Healthman] pers.comm., Oct 2019), by 2019 the difference in these premiums was more than five-fold. (data on file)

Study objectives

Whilst public sector data and trends in professional indemnity premiums suggest that claims for cerebral palsy have been driving the burgeoning insurance burden of O&Gs in the private sector, there are no empirical data to support this hypothesis. Implementation of effective controls of run-away litigation costs, including medical liability reform policies and quality improvement strategies, are furthermore hampered by lack of relevant data.[7],[8] To obtain a better understanding of the factors that may have contributed to the sharp increases in professional indemnity fees for O&Gs in South Africa's private sector and provide a platform for further research and the design and prioritization of practical solutions, the objective of this study was to analyse trends in medico-legal complaints against these practitioners and identify risk factors for patient dissatisfaction and medical negligence within the group.

Methods

Study design

This was a retrospective, observational study of current and historic medico-legal insurance notifications by O&Gs in South Africa's private practice. Data were sourced from Constantia Insurance Company, a dominant professional indemnity provider.

Measurements

All medico-legal cases on file were dated and categorized in terms of insurance case type and clinical parameters. Incident date referred to the year in which an incident relating to a case occurred. Notification date was the year a doctor became aware of a medico-legal dispute or potential medico-legal dispute in relation to such case and reported it to the insurer. Regarding case type, the most recent and relevant legal status of a case was defined, taking into consideration previous insurers' classification, personal updates from the practitioner shared during policy application, underwriting and claims management processes at Constantia, as well as case-related financial data, where available. Case types included summons with or without paid settlements, letters of demand, requests for records, regulatory

investigations, subpoenas, written complaints, inquests, notifications of circumstance and general requests for advice. In terms of clinical parameter coding, the main identifiable factor(s) underlying a complaint were defined by the clinical researcher using best available information. These could include alleged or actual clinical error, unethical behavior, clinical circumstance and/or sub-optimal outcome. Associated procedure-type was classified, where applicable. All cases were coded to indicate whether they were related to pregnancy (obstetrics), including antenatal, peripartum and postnatal care, as well as management of early miscarriages, ectopic pregnancies and terminations of pregnancy.

Analysis

Python Script was used to calculate annual medico-legal risk exposure on the basis of individual doctor's year of entry into private practice. This was used to estimate trends in relation to case incidence over time. A practitioner-driven database was furthermore generated which included non-identifiable practitioner-related demographic information, as well as years of risk exposure and count of cases per case type for a 10-year period from 2009 to 2018. This data source was used to assess medico-legal risk across practitioners. Only practitioners who had been in private practice for more than two years were included to reduce underestimation of case incidence for recent entrants into private practice, given the time lag between a clinical incident and a subsequent medico-legal enquiry or demand.

To avoid potential duplication of cases and undue linking of irrelevant cases, some cases were excluded from the final analysis, for example investigations relating to claims against third parties like the State or Road Accident Fund (RAF). Descriptive analyses were generated in Excel, Microsoft Office 365 ProPlus.

Ethics approval

Approval to conduct the research was granted by the Research Ethics Committee of the University of Cape Town. Confidentiality of practitioner-related information was safe-guarded throughout the study. Only the primary investigator as employee of Constantia Insurance had access to raw data.

Results

Doctor demographic information

Cases of 521 O&Gs were reviewed, with demographic characteristics of these practitioners depicted in table 1. For two doctors, demographic data was incomplete. Taking into consideration that there are an estimated 769 O&Gs in private practice,[9] this constitutes the medico-legal case histories of more than two thirds of practitioners in this specialty group in the South African private sector.

Category	Variable	n (%)
Gender	Male	308 (59%)
	Female	213 (41%)
Age	<45 years	193 (37%)
	45 – 54 years	147 (28%)
	55 – 64 years	126 (24%)
	>\= 65 years	54 (10%)
Years in private practice	</= 2 years	63 (12%)
	> 2 years; =/< 10 years	177 (34%)
	>10 years	281 (54%)
Province of practice	Gauteng	215 (41%)
	Western Cape	123 (24%)
	Kwazulu Natal	80 (15%)
	Other	101 (19%)

Table 1. Demographics of O&Gs contributing medico-legal case histories to analyses

Case types

Following removal of duplicate cases, and investigations and complaints against third parties like the State, 1848 cases were considered for inclusion in various analyses. Of these, 1068 were associated with documented patient complaints, ranging from written complaints, enquiries by the Health Professions Council and Office of Health Standards Compliance, requests for records to investigate a potential claim, letters of demands and summonses. For the remaining 780, there was no evidence of patient dissatisfaction, with the majority being notifications of circumstance in the context of claims-made as opposed to occurrence-based

indemnity cover. These notifications are part of the reporting that the insurer requires doctors to make in order to secure indemnity cover should there be a future claim. Whilst all reported patient complaints formed the basis for describing historic trends in terms of annual incidence of medico-legal cases, as well as clinical circumstances relating to settled claims, data sub-groups limited to cases from 2009 and subsequent years were analysed to estimate the contribution of obstetric versus gynaecological cases and the contribution of individual O&Gs to the medico-legal case burden amongst this group of specialists in the private sector more recently. Number of cases by case type and as included in the various analyses is summarized in table 2.

	Case type				**Number of O&Gs contributing cases**
	Demands with known settlements	Demands	Cases with evidence of legal and/or regulatory engagement by the patient	Cases with evidence of patient dissatisfaction	
Total study population All cases (patient complaints) for all O&Gs	86	305	845	1068	521
Sub-group 1 Cases from 2009 for all O&Gs	55	245	727	935	521
Sub-group 2 Cases from 2009 for O&Gs in private practice >2years	55	228	665	849	458

Table 2. Number of cases by case type included in various analyses reported

Annual case incidence trends

There was evidence of a sharp increase in medico-legal investigations and complaints against O&Gs providing services in the private sector from about 2003 to 2012. Since 2012, these activities have generally remained high (see figure 1). The higher number of requests for records relative to demands in 2016 and 2017 compared to previous years is likely to reflect delay in summons following a request for records, as well as lag in insurer update in this regard. Rate of increase in patient dissatisfaction following professional care rendered appeared similar for obstetrics and gynaecology. Figure 2 represents annual trends of all obstetric and gynaecological complaints reported to the insurer. Pregnancy status was unknown in 24% of cases.

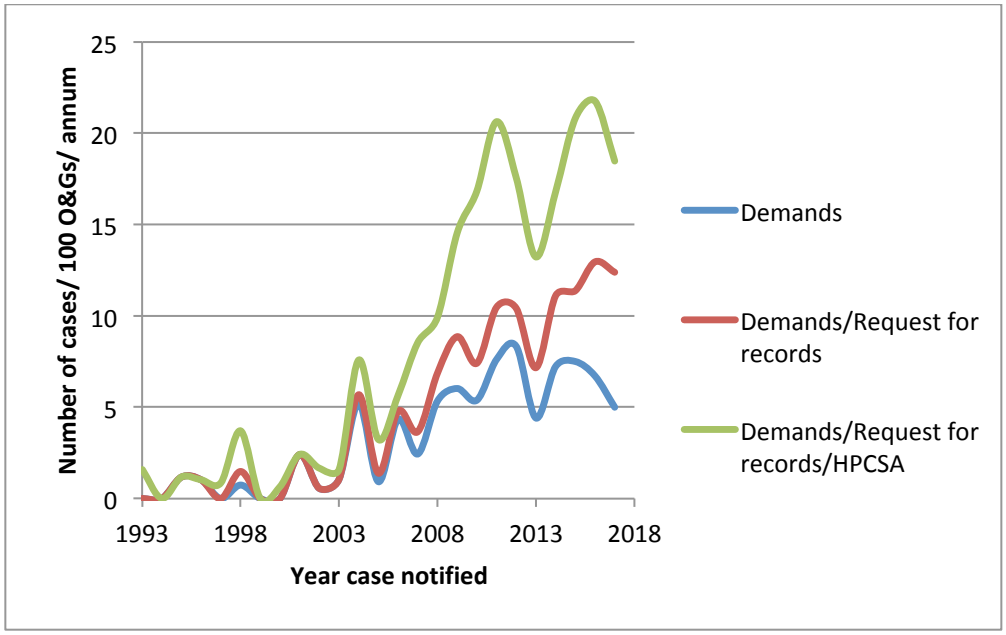

Figure 1. Annual incidence of medico-legal investigations and complaints

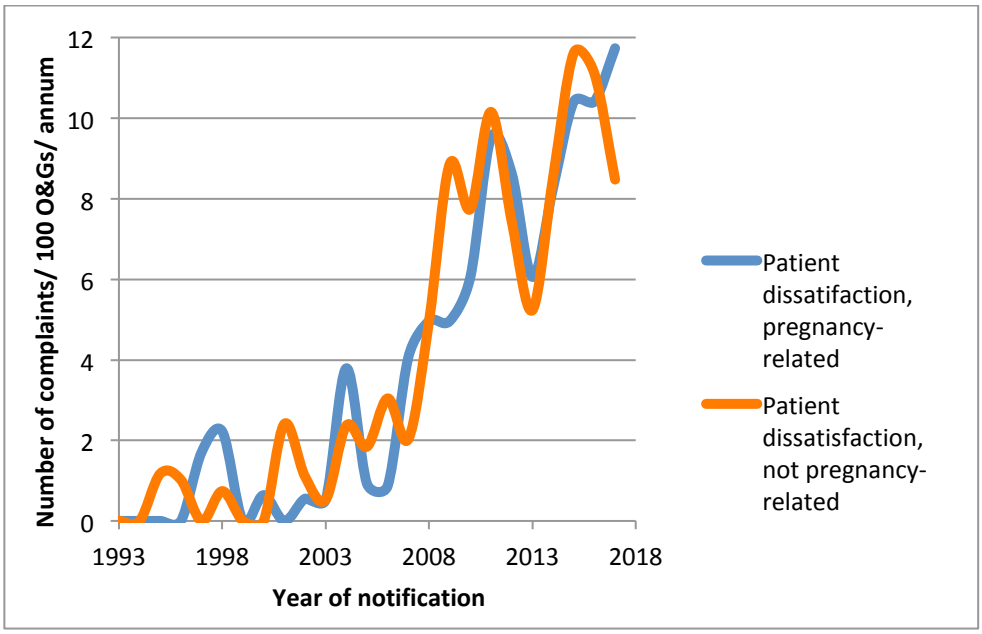

Figure 2. Annual incidence of pregnancy versus non-pregnancy related patient complaints

Obstetrics versus gynaecology cases

Whereas doctors were more concerned about the risk posed by obstetric cases, more gynaecology cases resulted in actual claims and settlements. For cases from 2009 to present where associated pregnancy status could be identified, and which included all cases notified to the insurer, 59% were related to obstetrics. This ratio, however, switched where only patient demands with or without settlements were analysed, with 42% of demands accounted for by obstetrics. Most paid claims (76%) were related to gynaecological problems. Pregnancy status was unknown for 10 (18%) settlements, 23 (9%) demands, 140 (19%) patient complaints associated with regulatory and/or legal engagement, 207 (22%) of all reported patient complaints and 292 (17%) of all notifications. Figure 3 represents proportion of different medico-legal case types reported over the past 10.5 years that relate to obstetric as opposed to gynaecological care.

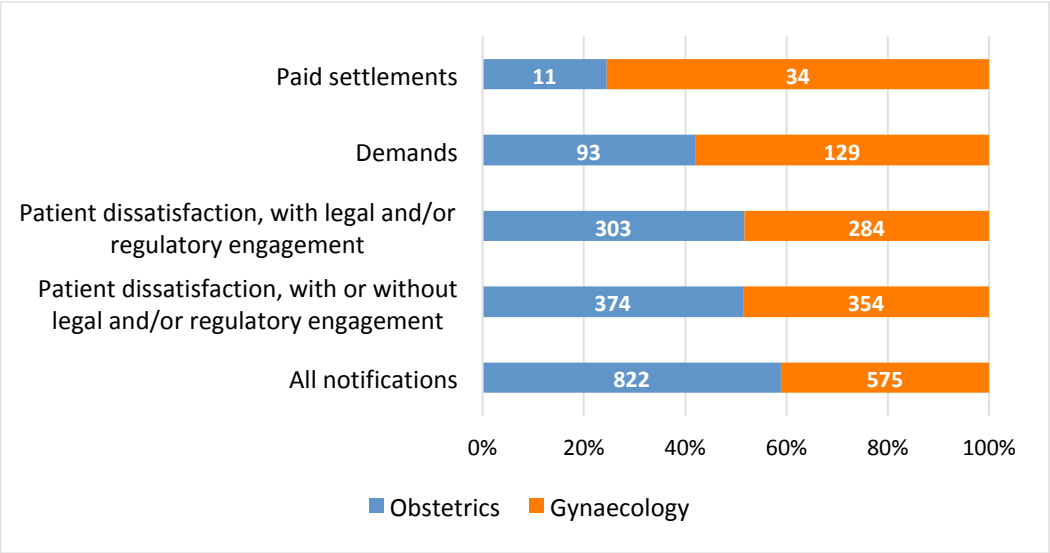

Figure 3. Obstetrics and gynaecology-related cases: 2009 to 2019

Case etiology

Of 50 gynaecological cases settled, 46 (92%) were procedure-related, of which 41% were as a result of injuries to internal organs and vessels during surgery. Further injuries may have been included in the more generic category of post-operative complications that included post-operative hemorrhage, fistula formation and sepsis. Failed sterilisations accounted for 12% of all settlements.

Of the 19 obstetric cases settled, almost all emanated from the intrapartum and immediate post-partum period. About half were for birth-related neurological injury of the newborn. In terms of clinical outcome, 6/69 cases (9%) were in relation to maternal death or death of a gynaecological patient. No known settlements were associated with neonatal deaths. For 17 paid settlements (20% of cases), there was insufficient clinical information to make a reasonable assessment of clinical circumstances that led to a claim. Full details are shown in tables 3 and 4.

	Case etiology	Number of cases
Procedure-related complications	Procedure-related injury, internal organs/vessels	19
	Post-operative complications, including hemorrhage, sepsis and fistula formation	7
	Failed and/or inadequate procedure	6
	Retained surgical products/swabs	4
	Surgical burns	3
	Multi-factorial/unknown	3
	Mesh-and slings related complication	2
	Inadequate consent	1
	Cosmetic dissatisfaction	1
Non-surgical complaints	Delayed and/or incorrect diagnosis	2
	Incorrect prescriptions	2
	Total	50

Table 3. Etiological factors associated with gynaecology-related paid claims

Pregnancy period	Case type	Number of cases
Antenatal	Missed fetal abnormality	2
	Cervical cerclage removal	1
Peri- and post-partum	Birth hypoxia/severe neurological injury of the newborn	9
	Suturing of 3rd degree perineal tear	1
	Caesarian section, ureteric injury	1
	Caesarian section, maternal death due to sepsis	1
	Caesarian section, retained swab	1
	Post-partum hemorrhage/retained products of conception with hysterectomy	2
	Maternal death due to fibroid degeneration	1
	Total	19

Table 4. Etiological factors associated with obstetric-related paid claims

To gain further insights into the dominant drivers of claim burden as determined by case frequency, regulatory and legal investigations and demands over an approximate 10.5-year period starting in 2009 were interrogated.

Intra-operative injuries to internal organs and vessels

Given that at least 29% of settled cases related to major intra-operative injuries, all demands in this regard over the past 10.5 years were further analysed in terms of associated procedure and injury types. Where surgical approach was listed, laparoscopy was identified more frequently in association with these injuries than open procedures. Bowel injury was the most common site of injury in cases litigated. Full details are shown in table 5.

	Known injury to internal organs and vessels (site of injury)
Laparoscopic gynaecological procedure	23 (12 bowel, 6 ureter, 2 bladder, 2 blood vessel, 1 unknown)
Abdominal/vaginal hysterectomies/oophorectomies	15 (4 bowel, 6 bladder, 4 ureter, 1 unknown)
Hysterectomies/oophorectomies*	16 (4 bowel, 6 bladder, 5 ureter, 1 urethra)
C/S	11 (6 bowel, 2 bladder, 2 ureter, 1 other)
Sterilization (known laparoscopic excluded)	1 (unknown)
Sterilization, laparoscopic	1 (bowel)
D&C/TOP	1 (bowel)
Endometrial ablation	1 (bowel)
Hysteroscopy	2 (bowel)
Contraception	1 (uterine and bowel perforation due to Mirena)
Unspecified/other procedures *	2 (1 bowel, 1 ureter)
Total	74

*laparoscopic status unknown

Table 5. Analysis of intraoperative injuries associated with claims from 2009 to 2019

Birth trauma resulting in severe neurological injury of the newborn

As number of demands for birth-related trauma resulting in severe neurological injury of the newborn was low in absolute terms, requests for records were included in a sub-analysis to identify claim trends in terms of this adverse outcome. Whereas no obvious trends of medico-legal activity over a 10-year period could be identified, 2017 was associated with an increased incidence of request for records compared to previous years (see figure 4). Late enquiries into births may have contributed to this finding (with one event notified as a result of a request for records 14 years and another 17 years previously). Whereas details regarding circumstances leading to alleged birth-related trauma were only available for a limited number of cases, the contribution of alleged hospital errors like failure to monitor patients during labour, failure to report adverse cardiotocography (CTG) readings to the responsible obstetrician, and/or failure to facilitate theatre access for purposes of emergency Caesarian section was evident in multiple cases. Figure 5 indicates number of cases where hospital failures are alleged to have contributed partially or fully to poor fetal outcomes (excluding mortality). Other than hospital failures, problems with availability of anaethetists during emergencies were cited in two recent cases.

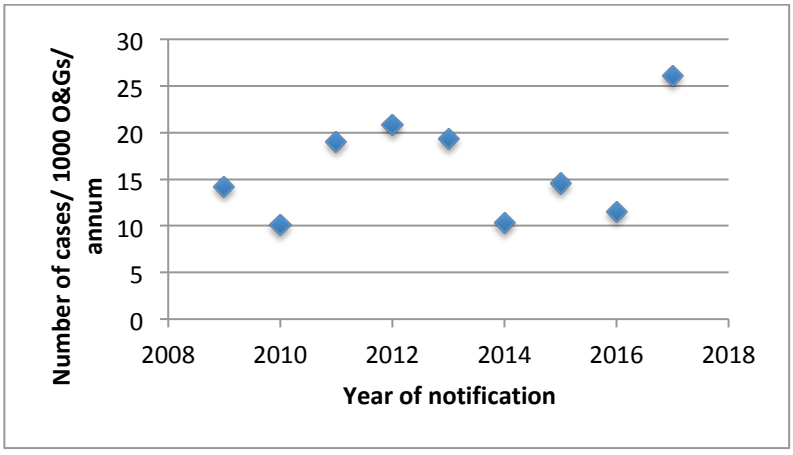

Figure 4. Annual risk-adjusted incidence of requests for records and demands relating to severe birth-related neurological injuries of the newborn

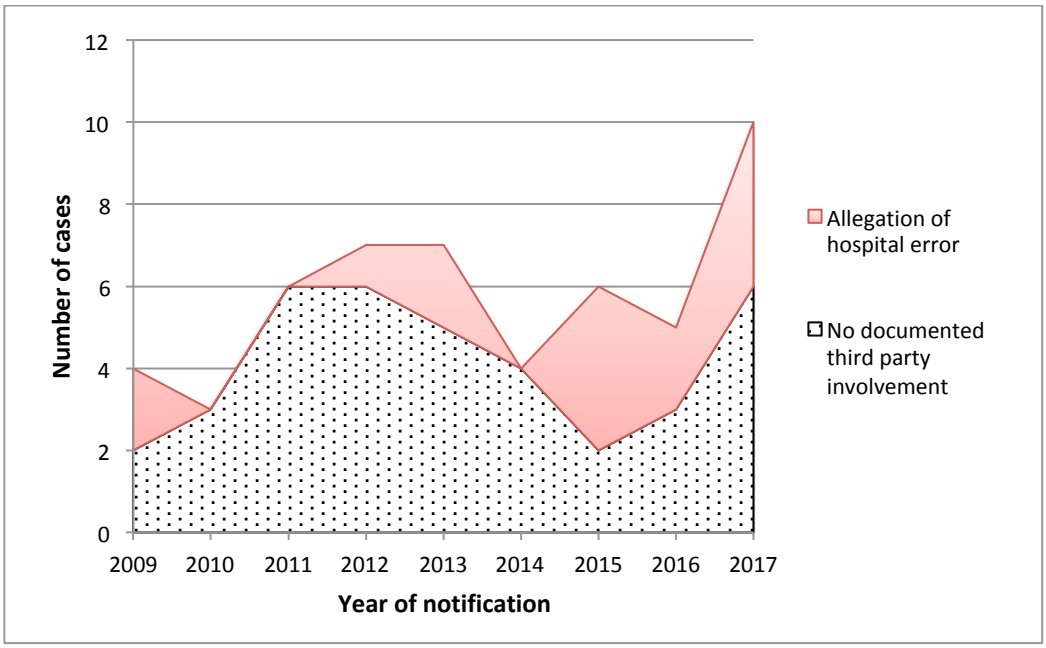

Figure 5. Annual number of cases of medico-legal investigations and demands relating to severe birth-related injuries of the newborn

(*Note*: Category 'no documented third-party involvement' may include cases of alleged hospital and/or other system failure. Not all cases were reported to the insurer with adequate detail for contributing factors to be adjudicated)

Distribution of medico-legal risk amongst O&Gs

To understand the contribution of individual practitioners to case burden, average annual case rate over a 10-year period for all practitioners who had been in practice for more than two years was calculated. Cases were defined as demands, regulatory investigations and requests for records. Where a demand was associated with a paid settlement, it was double counted. Average case rate per practitioner was estimated by dividing the weighted number of claims for a 10-year period from 2009 by years of risk exposure as a specialist in private practice. Results are depicted in figure 6. Furthermore, 203/458 O&Gs (44%) had no cases reported. Of these, 149 had been in practice for at least five years and 89 for the full 10-year period of study. At the other end of the spectrum, 9 doctors were identified who reported at least one case per annum. 7 of these practitioners had been in practice for eight years or more. Another 2 had just started out in practice. 50/458 (10.9%) of O&Gs accounted for 138/228 (60.5%) of demands during the study period.

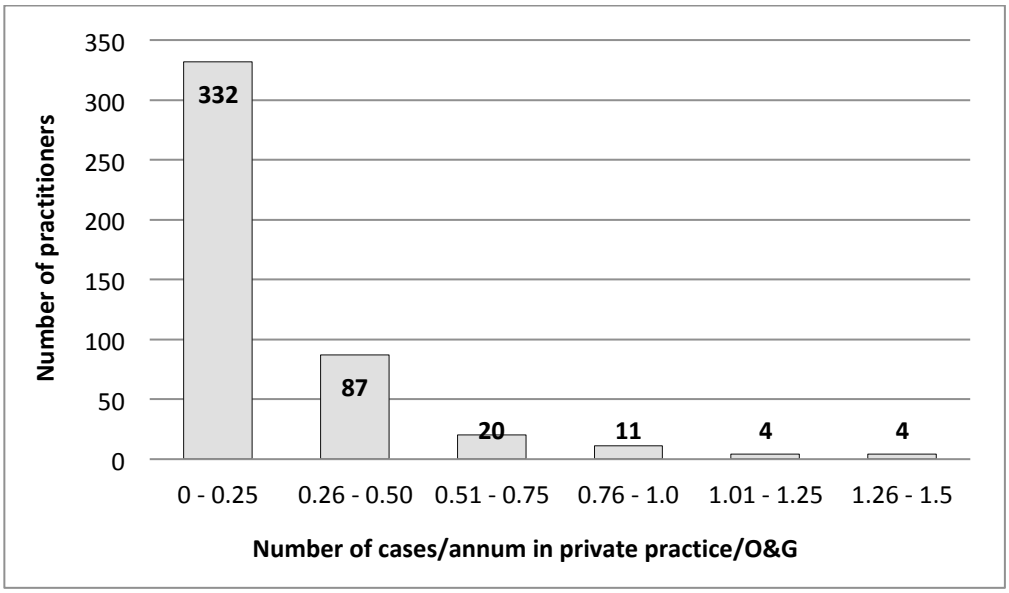

Figure 6. Average annual incidence of summons, requests for records and HPCSA complaints for duration in private practice per O&G

Discussion

The financial impact of medico-legal developments in South Africa is threatening the progressive realisation of universal health coverage. Whilst government is looking to mobilize additional funds and human resources as part of its National Health Insurance scheme, burgeoning claims of medical negligence in the public sector are ironically usurping health care budgets ear-marked for service delivery. In the private sector, exponential increases in professional indemnity fees are threatening the viability of professions like obstetrics and gynaecology. To stabilise the health care industry, diverse solutions ranging from reform of the medical malpractice litigation system and regulatory framework, to clinical quality improvement programmes and new indemnity models need consideration.

The focus of this study was to support improvements in health care delivery as a basis for controlling litigation costs. Other than seeking compensation for actual losses, pain and suffering or the provision of future care, one of the reasons patients litigate is to prevent similar events in future.[10] The legal system is thus seen as a vehicle to hold the health care system accountable and in check. In the United States, where medical liability reform has been on the national agenda for an extended period, the debate regarding liability cost control

has shifted to include patient safety improvement. Not only can medical liability reform impact clinical practice and with that the quality and cost of care delivered to patients, but perceived errors in the delivery of health care are at the core of the medico-legal challenge. [11] Furthermore, cases that are litigated are said to make up 'the tip of the iceberg' of clinical errors. Based on studies in the United States, it has been estimated that only 2-3% of patients injured by negligence file claims. The need for a sound understanding of 'where things go wrong' in the health care delivery system is thus important for purposes of designing and prioritising effective interventions aimed at the primary prevention of litigation. Whereas wrong actions by individuals like 'slips, lapses, fumbles, mistakes and procedural violations' underpin errors, it has been argued that failure to address weaknesses in the system that provoked or failed to prevent former will impede prevention of similar errors in future. [12] As maintained by Reason,[12] the majority of adverse events involve a combination of 'active failures' and 'latent conditions'. Latent conditions, also referred to as 'resident pathogens' within the system, reflect decisions made by policymakers and top-level management that define the context within which health care practitioners offer their services. In terms of errors on the ground, Kravitz et al differentiate between patient management problems, technical performance inadequacies and failures of team work as a result of poor communication between members of the medical and nursing teams.[13] Medico-legal data is being harnessed in various parts of the world to assist with the identification of medico-legal risks and associated opportunities for risk interventions.[14], [15], [16], [17], [18], [19]

Following this first empirical research investigating claims against O&Gs in South Africa's private sector, the relatively high number of demands and settlements for gynaecology- versus obstetric-related care was unexpected. Contrary to experiences reported from other countries, gynaecological rather than obstetric care appears to have been driving claim burden from the perspective of claim frequency. In Saudi Arabia, 80.7% of claims were related to obstetrics, with higher ruling in favour of the plaintiff in 61% of cases, as opposed to 18% in gynaecology.[17] In Spain, 61.9% of O&G claims involved obstetrics.[18] Twice as many claims were received for obstetric as opposed to gynaecological care by the National Health Service in the UK in 2016/2017 (10% versus 5% of all claims received).[20] A review of medical malpractice cases on file in the Forensic Association in Turkey indicated that 96% of O&G

claims were in the context of obstetrics versus 4% for gynecology.[21] In South Africa's public system, at least 76% of O&G claims are related to obstetrics. Whereas direct comparison of obstetric versus gynaecology risk across countries is difficult due to lack of a common definition, gynaecology cases in this study were classified in their narrowest sense. For example, therapeutic abortions were classified in the obstetric category.[13],[21] This means that we may have slightly underestimated the proportion of gynaecological claims, suggesting that the divergence in our findings versus other countries may be more pronounced than described here.

Regarding cerebral palsy, this is a dominant driver of medico-legal costs in many health care systems.[18], [20] Other than being associated with high quanta of demands, severe neurological deficit of the newborn as a result of alleged birth injury was also the most frequent context of settled obstetric-related claims in this study. Whilst the contribution of system failures could not be quantified adequately, clear problems in this regard were documented, including failure to monitor fetal wellbeing during labour, failure to report fetal distress to the attending obstetrician and lack of availability of theatre staff and /or anaesthetist. Based on a recent analysis of 200 South African public sector claims where intra-partum care was deemed to be substandard, failure to monitor fetal distress was evident as the main etiological factor in 43% of cases and failure to respond to fetal distress in another 26% of cases.[22] Errors with fetal heart monitoring were also recognised as the dominant theme amongst CP claims abroad.[20],[23]

In terms of gynaecological care, the high proportion of claims and settlements relating to gynaecological surgery, especially injury to internal organs during laparoscopic procedures, but also open surgery, raises questions. Concerns relating to this finding are particularly relevant taking into consideration a recent report by the South African Society of Surgeons in Training (SASSiT) that many registrars feel ill-prepared for independent practice, particularly in the field of minimally invasive surgery.[24] The need for training to be reviewed in the context of laparoscopic surgery has also been identified in other parts of the world.[25],[26] One of the key recommendations in this regard has been the integration of simulator training and standardised assessments prior to real-time operating room experience into national curricula

and board certification processes. Whereas technical dexterity is important for any surgeon, specific psychomotor skills are required for the safe and effective performance of laparoscopically guided procedures. Remote handling of instruments without tactile feedback, two-dimensional depth perception and fine motor skills in relation to the use of long instruments and the fulcrum effect - which refers to tool endpoints moving in the opposite direction to the surgeon's hands - are skills that make these procedures particularly challenging. Only those whose skills have been validated in vitro should be able to proceed with operations on patients and qualify for certification. In a study analysing 133 laparoscopy-related gynaecology claims over a 20-year period, visceral and vascular injuries accounted for 82% of these. More than three quarter (77%) related to basic rather than advanced laparoscopic procedures like diagnostic laparoscopy, tubal ligations and salpingo-oophorectomies, supporting the need for a basic skill set even for the simpler procedures.[27]

Regarding the unequal distribution of medico-legal risk amongst practitioners, this has been described by others.[28], [29], [30] Based on the findings of this study, any O&G in private practice who on average has one or more requests for records, regulatory complaints or claims in any two-year period should reflect on and address potential contributing factors which may include technical standards of work, behavioural issues influenced by the practitioner's attitude, communication skills and accessibility, as well as environmental influencers. Contrary to some practitioners' beliefs, not only paid, but also unpaid claims have predictive value of future demands.[31]

Study limitations

Whilst the study was based on real-life data, every effort was made to correct inadvertent data inaccuracies and gaps by correlating previous insurers' case histories with self-reported incidents by doctors. With case types not categorized in a standardized manner across the industry, some cases had to be re-classified using best available evidence. In addition, information on incident dates was limited, therefore analyses had to rely on notification dates. Given different expected time lags between gynaecology- and obstetric-related incidents and claims – with obstetric claims often delayed beyond three years following an adverse event –

this may have slightly skewed the results of some of the time-based analyses. Where year of entry into private practice by practitioners was unknown, an assumption was made that this occurred the year after registration as a specialist, leading to potential over-estimation of a practitioner's number of years in private practice. Overall, the potential limitations are unlikely to have influenced the validity of key findings in a meaningful way.

Conclusion

Contrary to other countries that have experienced steep increases in medico-legal demands, empirical data depicting private sector O&G medico-legal trends and analyzing these to guide and lobby solutions have been scarce in South Africa to date. Whereas multidimensional reform that spans across the healthcare delivery, litigation and insurance systems is required to address the impact of medico-legal trends on obstetricians, this study was aimed specifically at understanding factors within clinical practice itself that may be predisposing to claims against practitioners, as a basis for defining and prioritising quality improvement solutions. Taking into consideration relative increases in professional indemnity fees for obstetrics and gynaecology over recent years, as well as international experiences, the high frequency of settled claims relating to gynaecological procedures was unexpected. Reasons for this should be explored and should include an analysis of surgical complications for main procedure types in the private sector. Review of aspects of surgical training and accreditation standards in O&G may also be called for, together with the consideration for surgical mentorship programmes. In terms of claims relating to severe birth trauma, more research is required to understand and quantify system failures that may be contributing to medico-legal risks in this regard in the private sector and the impact of these on obstetric practice. The high concentration of medico-legal complaints amongst a small group of practitioners furthermore highlights the need for doctor-focused solutions, including strengthening of peer review and regulatory oversight.

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Part D: Policy Brief

HEU Policy Brief
Health Economics Unit – University of Cape Town
Jan 2020

Data key to unlocking medico-legal risk reduction strategies

School of Public Health & Family Medicine

University of Cape Town

South Africa's medico-legal crisis is first and foremost an obstetric crisis

Medico-legal trends are threatening the delivery of key health care services. For some surgical specialties, professional indemnity insurance premiums in the private sector have skyrocketed over the last ten years, making the delivery of these services potentially unviable. Doctors have furthermore expressed that fear of lawsuits is making them reconsider their future in clinical practice, threatening the supply chain of service delivery. The same fears are leading to defensive clinical practices, which include unnecessary clinical investigations and interventions to protect the doctor. In the public sector, demands for financial compensation following alleged medical negligence have spiraled out of control. If these trends continue, potential liabilities to cover medical malpractice claims may soon exceed the State's annual health care budget. Whereas key factors that have contributed to the current status quo are poorly documented, the medico-legal focus in both sectors is on obstetric-related care.

In the **private sector**, professional indemnity premiums are highest for those offering obstetric services.

In the **public sector**, the greatest burden on government's health care budgets is posed by demands relating to poor obstetric outcomes.

Without decisive action, legal pursuit of the health care sector by aggrieved patients and those harmed as a result of negligence will undermine the delivery of essential health care services, first and foremost for maternal care.

About the study:

The research was conducted by Bettina Taylor to fulfil the requirements for a MPH (Health Economics) from the University of Cape Town.

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Stefan Strijdom (Mast Analytics) and Nicolas Taylor (BSc student) who provided data management support

Board of Healthcare Funders (BHF) who authorised use of data from the Practice Code Numbering System (PCNS)

Introduction

In the private sector, professional indemnity fees for obstetricians and gynaecologists (O&Gs) have increased by an approximate factor of 10 over a 10-year period, threatening the viability of private obstetric care. The high Caesarian section rate in South Africa's private sector has furthermore been ascribed, at least partially, to fear of litigation and resultant defensive practice. In the State, where contingent liabilities for alleged medical negligence have increased exponentially over recent years - from about ZAR56.96 billion in 2017 to ZAR98 billion in 2019 - more than half of claims relate to obstetrics and gynaecology, of which about three quarter are for cerebral palsy as a result of alleged negligence. Based on these findings, there is a sense that hypoxic birth-related injury of the newborn is driving litigation risk across the industry. Despite the ominous implications of this medico-legal landscape for the supply side of health care, empirical data to understand trends and their etiologies are nevertheless lacking. Without these, the appropriate prioritization, design and implementation of effective risk management interventions like medical liability reform and patient safety initiatives are hampered. By addressing root causes of adverse clinical outcomes and patients' experiences that lead to dissatisfaction and engagement of the legal system, primary prevention of litigation as a result of quality of care improvements can be achieved. Such root causes include both individual, as well as system failures. Whereas wrong actions, poor communication and lack of visible empathy may lead to adverse events and patients' negative health care experiences, weaknesses in the system that provoked or failed to prevent former will impede prevention of similar errors in future.

These weaknesses reflect decisions made by policymakers and top-level management and could, for example, include hospital protocols, clinical training standards and accreditation and financing models.

The need to identify, understand and address important gaps in health care delivery as perceived by patients and/or ruled on by the legal system as a mechanism to reduce litigation costs thus prompted an exploration of O&G-related medico-legal data emanating from care delivered in the private sector.

Box 1

Professional indemnity cover offered by private insurers at an annual premium provides support to doctors in the event of medico-legal investigations like inquests, regulatory enquiries and lawyers' requests for records to investigate potential claims, as well as demands for compensation arising out of a practitioner's professional practice. It also covers financial settlements where indicated. Defense and settlement of claims arising out of State practice are, however, excluded, as the State as the employer is liable in these instances.

It is important for doctors to have professional indemnity cover as

- It safeguards them when faced with medico-legal enquiries and challenges and/or when they know they have erred inadvertently in their capacity as health care providers
- It provides for compensation to patients that have been harmed as a result of negligence by health care professionals

Methodology

Given the lack of empirical studies examining the steep increases in professional indemnity fees for O&Gs in South Africa's private sector, a retrospective, observational study was conducted with the objective of describing claim patterns that have underpinned these increases, as well as identifying potential risk factors for claims for purposes of guiding future research and risk management solutions, in particular patient safety initiatives.

All incidents declared to Constantia Insurance Limited, a local professional indemnity insurer who holds demographic and claims data on about two-thirds of O&Gs providing clinical care in South Africa's private sector, were categorized in terms of medico-legal case type (see medico-legal notifications, box 2), as well as clinical parameters. In terms of clinical parameter coding, the main identifiable factors underlying a complaint were defined by the clinical researcher using best available information. These could include alleged or actual clinical error, unethical behavior, clinical circumstance and/or sub-optimal outcome. Associated procedure-type was classified, where applicable. All cases were coded to indicate whether they were associated with pregnancy for purposes of differentiating obstetric- and gynaecology-related cases. To allow for risk-adjusted calculations of case incidence, year of entry into private practice was estimated for all practitioners.

Key findings

Visible increases in medico-legal investigations and complaints slightly

Box 2: Medico-legal notifications

The type of cases that are notified by doctors to their indemnifier include

- Demands by patients and/or their families via lawyers for compensation following dissatisfaction with care received and/or the clinical outcome following such care;
- Self-reported clinical errors;
- Inquests to determine cause of unexpected or unexplained patient death in the context of clinical care;
- Written complaints by patients;
- Formal investigations relating to care received by third parties appointed by patients. Where patients are aggrieved, they can
  - lodge a complaint with regulatory authorities like the Health Professions Council of South Africa or the Office of Health Standards Compliance; or
  - appoint a lawyer to request patient records to conduct an independent inquiry.

Where doctors are insured on a claims-made basis, they may also report adverse outcomes, irrespective of whether they perceive there to have been inadequate care. This is to ensure insurance protection should the need arise in future.

Whereas all incidents notified to indemnifiers may be indicators of suboptimal quality of care, they are also indicators of potential financial liabilities, especially where patients have already embarked on a formal regulatory or legal path. Even where no clinical negligence is proven, significant amounts of money may be required to defend such cases.

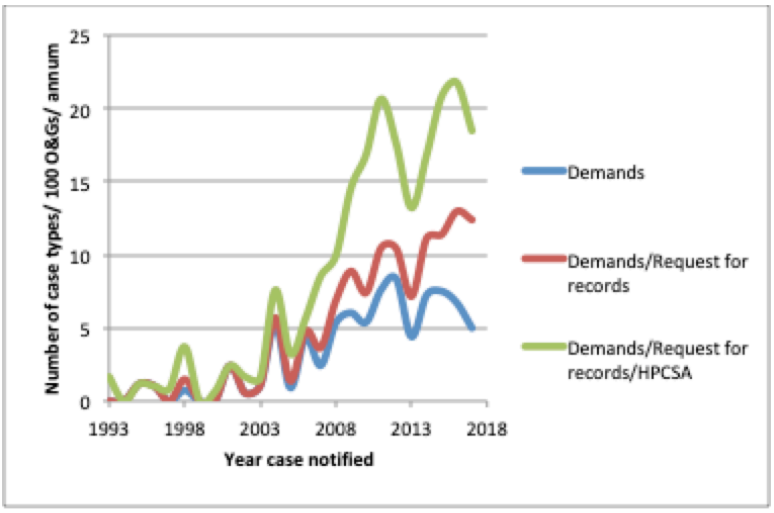

Figure 1. Annual incidence of medico-legal investigations and complaints

preceded rapid increases in professional indemnity fees over the past ten years (figure 1), with obstetric and gynaecological practices affected in a similar manner. Whereas doctors were more concerned about the risk posed by obstetric cases, which was anticipated, more gynaecology cases indeed resulted in actual claims and settlements (figure 2). Surgical complications, especially intraoperative injuries to internal organs and vessels, were associated most commonly with paid settlements. Where surgical approach was listed, laparoscopy was identified more frequently in association with iatrogenic injuries than open procedures.

Of 69 meritorious claims[1] against O&Gs, 12% were for retained surgical swabs or superficial burns.

Within obstetrics, almost all settlements emanated from the intra-partum and immediate post-partum period, with about half as a result of birth-related neurological injury of the newborn (9/19 settled obstetric cases). Alleged errors like failure to monitor patients during labour, failure to report adverse electronic fetal monitoring readings to the responsible obstetrician, and/or failure to facilitate theatre access for purposes of emergency Caesarian section were evident in numerous cases notified over a ten-year period following a request for records or a claim for alleged severe birth-related injury to the newborn. Poor availability of anesthetists during emergencies was another factor cited in more than one case where fetal outcome was poor. Given inadequate clinical information, however, the extent of third-party contributions and system failures to poor fetal outcome could not be quantified.

Clear outlier doctors in terms of average incidence (figure 3) and total number of medico-legal enquiries and complaints

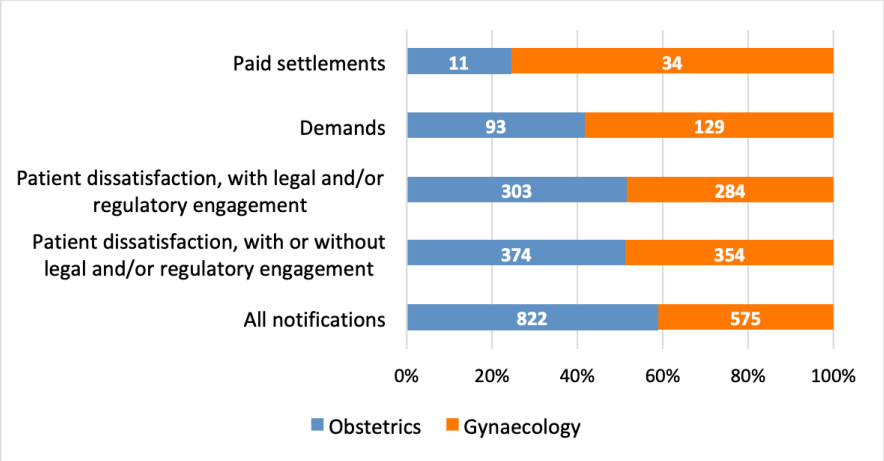

Figure 3. Obstetrics and gynaecology-related cases: 2009 to 2019

[1] These are demands with a settlement payment.

were furthermore identified. In the cohort of 281 practitioners in private practice for at least ten years, 89 (32%) had no associated regulatory complaints, requests for records or claims and 164 (58%) had not received a summons or monetary demand during the ten-year period studied. At the other end of the spectrum, 6 (2%) of practitioners had ten or more documented regulatory complaints, requests for records or claims against their name during the same period, and 5 (1.8%) had five or more actual claims. For practitioners in private practice for more than two years, 10.9% (50/458) accounted for 60.5% (138/228) of demands during the study period.

What do these findings mean?

The study confirms steep increases in the incidence of medico-legal investigations and complaints as a contributor to the rapid rise in professional indemnity fees experienced by O&Gs in the private sector. Following a previous report by the Medical Protection Society that claims across the industry increased by 35% between 2011 and 2016 for health care practitioners, risk-adjusted case incidence analyses showed that the upward trend in medico-legal activity for private practice O&Gs already started just after the turn of the millennium. The finding that claims for severe neurological deficit of the newborn as a result of birth-related injuries accounted for about half of obstetric-related paid settlements supports the notion that these claims have contributed towards financial trends, especially taking into consideration the high quantum of demand that may be associated. The research nevertheless raises questions regarding the extent of contribution of hospital failures to birth-related injuries and associated medico-legal burden of O&Gs, including unaffordable insurance premiums.

Unexpected was the high proportion of gynaecology versus obstetric claims, which is inconsistent with international findings and contrary to experiences in South Africa's public sector where obstetric claims dominate. Whilst no conclusions can be drawn from this, the high contribution of iatrogenic injuries as part of such observation calls for further research into O&G-related surgical complication rates in the private sector, both in relation to other surgical specialties, as well as international peers.

In line with reports from other parts of the world, claims were concentrated within a small group of practitioners which points towards a need for doctor-focused interventions, effective peer review and strengthening of regulatory oversight of outlier doctors.

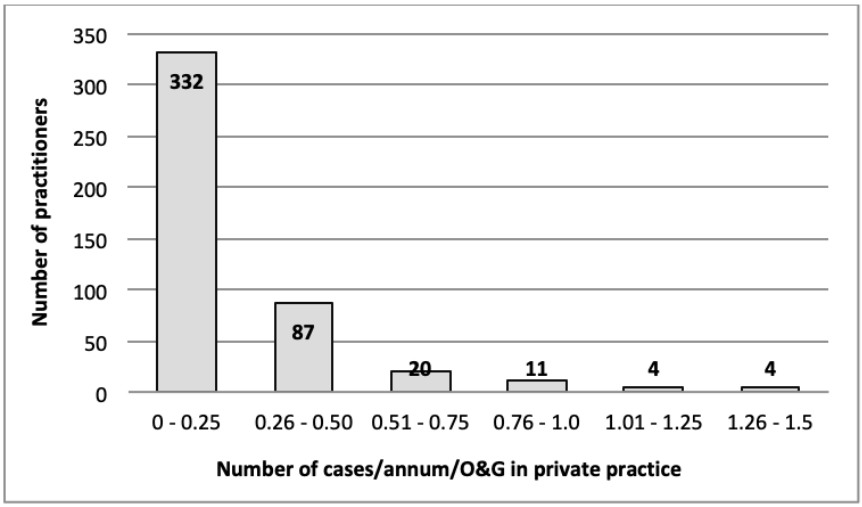

Figure 3. Average annual incidence of summons, requests for records and HPCSA complaints for O&Gs in private practice

Study limitations

This study was based on real-life data with its associated challenges of inadvertent data inaccuracies and gaps. Every effort was nevertheless made to correct for these by correlating previous insurers' case histories with self-reported incidents by doctors. With case types not categorized in a standardized manner across the industry, some cases also had to be re-classified using best available evidence. Where year of entry into private practice by practitioners was unknown, an assumption was made that this occurred the year after registration as a specialist, leading to potential over-estimation of a practitioner's number of years in private practice. Some data sets were furthermore incomplete due to inconsistent reporting of case details. In addition, the research was based on analysis of years during which medico-legal incidents were notified as opposed to years in which incidents occurred. Given differences in expected time lags between gynaecology- and obstetric-related incidents and claims – with obstetric claims often delayed beyond three years following an adverse event – this may have slightly skewed the results of some of the time-based analyses. All shortcomings were, however, taken into consideration during analyses. Overall, the limitations are unlikely to have influenced the validity of key findings and associated policy recommendations in a meaningful way.

Policy Implications

Based on findings of this research, which included review of the literature, key policy considerations relate to the need for better data to understand and manage medico-legal risks more effectively, together with the requirement for

enhanced peer review and regulatory oversight of health care providers.

Specific recommendations include the following:

Serious preventable adverse events that should never occur should be reported. Patient safety is a key component of the medico-legal challenge.
The need for reporting of patient outcomes data has already been identified by the Competition Commissioner following the recent Health Market Inquiry into private health care. To support value-based purchasing[2], establishment of an independent central body where hospitals and independent practitioners should submit patient outcomes data has been put forward. Rather than duplicating similar efforts for purposes of targeting medico-legal risk reduction strategies, however, data collection and reporting initiatives should be streamlined to avoid

[2] Value-based purchasing is a payment model of health care providers that links reimbursement to performance, which includes adherence to specific quality measures.

potential data conflicts and administrative inefficiencies. Notwithstanding the recommendations of the Health Market Inquiry, information of a sensitive nature should furthermore remain privileged, and only be available on a confidential basis to contracted risk management partners and funders and in a non-identifiable manner to academic researchers.

Aspects of surgical training and accreditation standards for O&Gs should be reviewed and surgical mentorship programmes considered.

Given the high proportion of demands and paid settlements for gynaecological as opposed to obstetric cases, especially as a result of surgical complications, further research is indicated in terms of patient outcomes following specific procedures in the private sector. A recent survey by surgical registrars also suggests that many do not feel adequately prepared for independent practice when they qualify as specialists, especially with regards to minimally invasive surgery.

Regular combined morbidity and mortality meetings should be promoted and supported by all stakeholders.

The private sector has been criticized for providing highly fragmented care where accountability may be poorly defined. Hospital-based care relating to obstetrics and gynaecological practice is one such example where emergency staff, nurses and midwives, hospital management, anaesthetists, pediatricians and O&Gs themselves may all be acting independently during care of a patient, creating significant opportunities for 'team error'. Given the high proportion of meritorious O&G claims that arise from in-hospital care, regular combined morbidity and mortality meetings amongst the various stakeholders are called for. Whilst these meetings form one of the pillars of the BetterObs Programme[3], they should not be confined to deliveries, as they provide important opportunities for self-audit, team learning and review of local protocols and processes in relation to all procedures. Ideally minimum standards for such meetings should be defined, which could then also provide opportunities for the allocation of Continuing Professional Development (CPD) points where adherence to such standards can be demonstrated.

Regulatory oversight by the Health Professions Council of South Africa needs strengthening.

The high medico-legal burden posed by a few doctors supports the need for more effective regulatory oversight of individuals who are outliers in terms of the risk they pose. Failure of the Health Professions Council of South Africa (HPCSA) to deliver on its mandate as a result of multi-system organizational dysfunction was highlighted by the Ministerial Task Team in 2015. To ensure patient safety, and with that mitigate medico-legal risks, the Task Team's call for reform should be heeded, in particular unbundling of the Council of South Africa (HPCSA) into at least two entities - the historic Medical and Dental Council, which includes specialists like obstetricians and gynaecologists, and a Health and Rehabilitation Council for the rest of the professional membership.

[3] The BetterObs Programme was launched by the South African Society of Obstetricians and Gyanecologists (SASOG) in 2016 with the objective of promoting safe ante- and intrapartum care and, with that also mitigating the risks of a successful lawsuit. Clinical protocols and guidelines and society-driven peer review to handle allegations of unprofessional conduct, repeated misconduct or members not following guidelines or protocols are key components.

The Need for Data-Driven Risk Management Interventions

To reverse the burgeoning financial burden associated with medico-legal trends, reform of the medical liability system, identification of opportunistic, vexatious and/or fraudulent claims and focused quality of patient care and practice management initiatives are called for.

Within the health sector, risk management is aimed at the prevention of claims, as well as the effective support of rapid and fair dispute resolution where patients are dissatisfied. This requires

- Constant improvements aimed at patient safety
- Promotion of effective and empathetic communication within the delivery of health care services
- Sound practice management that includes effective business management processes to support good patient care and proper recordkeeping

Hotspots for medical errors and high levels of patient dissatisfaction should be identified from medico-legal data and be used to focus the prioritization and design of risk management interventions at all levels: government policy, regulatory processes, institutional and funder protocols and individual behavior. Success of such a strategy is dependent on effective data collection and analysis.

The public sector should adopt a similar approach to data analysis and identification and prioritization of risk management opportunities as described in this research.

Given the significant differences between the public and private sectors, medico-legal risk management priorities will not be the same. The high proportion of gynaecological versus obstetric claims in the private relative to the public sector bears testimony to this.

Key resources

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Contact details for more information
bettinataylor2@icloud.com

Part E:
Appendices

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Buildin
Groote Schuur Hospita
Observatory 792
Telephone [021] 406 662
Email: shuretta.thomas@uct.ac.z
Website: www.health.uct.ac.za/fhs/research/humanethics/form

20 August 2018

HREC REF: 512/2018

A/Prof S Cleary
Health Economics Unit
Public Health & Family Medicine
Falmouth Building

Dear A/Prof Cleary

PROJECT TITLE: A RETROSPECTIVE, OBSERVATIONAL STUDY OF THE DETERMINANTS OF MEDICO-LEGAL INCIDENTS AMONGST OBSTETRICIANS AND GYNAECOLOGISTS IN THE SOUTH AFRICAN PRIVATE SECTOR (MPH Candidate - Dr B Taylor)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 August 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student Dr Bettina Taylor will also be involved in this study.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938